



AAHS-RDF

DEPARTMENT OF THE ARMY
OFFICE OF THE ADMINISTRATIVE ASSISTANT TO THE SECRETARY
U.S. ARMY HEADQUARTERS SERVICES
9301 CHAPEK ROAD
FORT BELVOIR, VA 22060-5605
FEBRUARY 04, 2020

Russ Kick
New England Anti-Vivisection Society
333 Washington Street
Suite 850
Boston, MA 02108
Sent via email: rkick.contractor@neavs.org

Dear Mr. Kick:

This letter is in response to your Freedom of Information Act (FOIA) request dated December 23, 2019. You are seeking records pertaining to the use of animals in research, teaching, etc. at the U.S. Army Medical Center of Excellence. Your request is being processed in accordance with Title 5 United States Code 552, The Freedom of Information Act. Your request was assigned case numbers FA-20-0748 / FP-20-007572.

Please be advised this office serves as the referral point and policy office for the Department of the Army Freedom of Information Act. Requests for information and documents under the purview of the Army are referred to the proponent agency for appropriate handling and the proponent of the requested records in accordance with Army Regulation 25-55, The Army Freedom of Information Act Program.

After conducting research, we are referring your request to the following activity for processing and direct response to you.

U.S. Army Medical Center of Excellence
3630 Stanley Road
JBSA Fort Sam Houston, TX 78234

You may check the status of your Freedom of Information Act request by going to <https://www.foia.army.mil/facts/casestatus.aspx> and entering FP-20-007572 in the Control Number box. Please note that once your request is received at the next agency(s) listed above it will be assigned a new Control Number that you will have to use to track the status of your request. If you have any questions regarding the processing of your request, please contact that activity.

Sincerely,

Annette Wormley
U.S. Army Freedom of
Information Act Office



DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL CENTER OF EXCELLENCE
3630 STANLEY ROAD
JBSA FORT SAM HOUSTON, TEXAS 78234-6100

Freedom of Information Act Office

20 April 2020

Mr. Russ Kick
New England Anti-Vivisection Society
333 Washington Street, Suite 850
Boston, MA 02108

Dear Mr. Kick:

This is in response to your Freedom of Information Act (FOIA) request dated 4 February 2020, that was referred to the U.S. Army Medical Center of Excellence (MEDCoE) by the Department of the Army FOIA Office, 9301 Chapek Road, Bldg 1458, Suite 1NW5705, Fort Belvoir, VA 22060-5605. Your request was given MEDCoE FOIA case number FP-20-0007 and Department of the Army FOIA case number FP-20-011365.

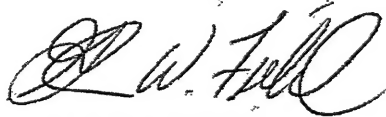
In your FOIA request it states you were seeking records as such; "This request concerns the use of animals in research, teaching etc. at the U.S. Army Medical Center of Excellence. For every Institutional Animal Care & Use Committee (IACUC) at the Center, we request the following: records seeking are specified in paragraphs 1a, 1b, 2a, and 2b." Attached to this memorandum you will find your FOIA request as submitted to the DA FOIA Office in its original form.

After a thorough search of all electronic computer and paper files belonging to and related to the IACUC program at MEDCoE there were no records located responsive to your request.

Sir, if you are dissatisfied with our conclusion, you may appeal to the Secretary of the Army through this FOIA office. If you decide to appeal at this time, your appeal must be postmarked within 90 days of the date of this letter. Please address your appeal to: Commander, U.S. Army Medical Center of Excellence (MEDCoE) Attention: Freedom of Information/Privacy Act Office, 3630 Stanley Road, Suite 357, JBSA Fort Sam Houston TX 78234-6100. Clearly mark the letter and envelope as "Freedom of Information Act Appeal" citing your FOIA case number FP-20-011365, and enclose a copy of this letter along with your appeal. Please state the basis for your disagreement with our decision, and the justification for such an appeal associated with your request to this Command. Or, you may email this FOIA office at; usarmy.ibsa.medical-coe.list.foia-request-owner@mail.mil using the same appeal procedures.

As this completes the processing of your request we are closing your case. If you have any additional questions your point of contact for this action is Glenn W. Field, FOIA Officer and Records Manager, Assistant Chief of Staff for Information Management, at (210) 221-6754 or (210) 643-5867.

Sincerely,

A handwritten signature in dark ink, appearing to read "Glenn W. Field". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

GLENN W. FIELD
Freedom of Information Act Specialist
Assistant Chief of Staff
for Information Management

FREEDOM OF INFORMATION ACT REQUEST REFERRAL

1. TO	<input checked="" type="checkbox"/>	A. U.S. Army Medical Center of Excellence 3630 Stanley Road, JBSA Fort Sam Houston, TX 78234
	<input type="checkbox"/>	B.
	<input type="checkbox"/>	C.
	<input type="checkbox"/>	D.
	<input type="checkbox"/>	E.
	<input type="checkbox"/>	F.
	<input type="checkbox"/>	G.
	<input type="checkbox"/>	H.

2. FROM DA FOIA Office RMDA 9301 Chapek Road, Bldg. 1458 Suite 1NW5705 Fort Belvoir, VA 22060-5605	3. ACTION OFFICER'S NAME & TELEPHONE NO. Annette Wormley COMM: (571) 515-0307	4. DATE 04 February 2020
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5. SUBJECT: Please see attached FOIA request.

6. REQUEST	<input checked="" type="checkbox"/>	A. FREEDOM OF INFORMATION ACT/KICK/R	7. CONTROL NO. FA-20-0748
	<input type="checkbox"/>	B. PRIVACY ACT/	PA
	<input type="checkbox"/>	C. RESEARCH/	RES

8. ACTION	<input checked="" type="checkbox"/>	D. Enclosed request is referred to you for review and response back to the requester. This request should be referred by your office to any other appropriate or subordinate agency you may determine to have cognizance over the information.
	<input type="checkbox"/>	E. Request this office is furnished a copy of action taken (Responsive letter only).
	<input checked="" type="checkbox"/>	F. Requester has been advised of this referral.
	<input checked="" type="checkbox"/>	G. Provide a proper "no records" response, with appeal rights, if after conducting a reasonable search, you fail to locate any documents responsive to this request.

REMARKS: Referral for your action and direct response to the requester.

NOTE:

Encl(s)
as

//signed//
ANNETTE WORMLEY
 Government Information Specialist
 U.S. Army Freedom of
 Information Act Office

Original FOIA request

FP-20-007572
FA 20-0748

From: Russ Kick <rkick.contractor@neavs.org>
Sent: Monday, December 23, 2019 1:44 AM
To: USARMY Ft Belvoir HQDA OAA AHS Mailbox RMDA FOIA
Subject: FOIA Request Generated from RMDA Website

First Name: Russ
Middle Initial:
Last Name: Kick
Company Name: New England Anti-Vivisection Society Phone Number: (520) 589-4776 eMail Address: rkick.contractor@neavs.org
Address: New England Anti-Vivisection Society Address (Line 2): 333 Washington Street, Suite 850
City: Boston
State: Massachusetts
Zip Code: 02108
Willing to Pay Fees: Up to \$25
Request: This request concerns the use of animals in research, teaching, etc. at the U.S. Army Medical Center of Excellence.

For every Institutional Animal Care & Use Committee (IACUC) at the Center, we request the following:

1a) According to The Guide for the Care and Use of Laboratory Animals (The Guide), 8th edition, all entities must have a system in place for anyone (insiders or members of the public) to report concerns regarding animal welfare at a facility. These reports are either made directly to the IACUC Chair or a designated representative, or they eventually are routed to the IACUC Chair/representative. We request all such reported concerns received by the Chair since January 1, 2019. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.)

1b) Further, for all such reported concerns deemed supported, we request the notification sent to the Institutional Official: The time frame is January 1, 2019, to present. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.)

2a) Per The Guide, all entities must have a system in place for investigators to notify the IACUC and/or attending veterinarian of adverse events, unexpected or unanticipated outcomes, violations of protocols, and other incidents involving animal welfare that occur during their studies/experiments. We request all such notifications received by the IACUC or AV since January 1, 2019. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.)

2b) Further, we request all notifications sent to the Institutional Official regarding these reported incidents. The time frame is January 1, 2019, to present. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.)

Response Letter to the Requester

From: Field, Glenn W CIV USARMY MEDICAL COE (USA)
To: rkick.contractor@neavs.org
Cc: Kidd, Timothy M CIV USARMY MEDICAL COE (USA)
Subject: Interim Response #1 - FOIA Request FA-20-0007 (New England Anti-Vivisection Society) - MEDCoE (UNCLASSIFIED)
Date: Thursday, February 13, 2020 12:07:30 PM
Attachments: FA-20-0748 referral packet to AMCOE - FOIA Request.pdf

CLASSIFICATION: UNCLASSIFIED

Mr. Kick,

Greetings. This is interim response number one (1) to your Freedom of Information Act (FOIA) request dated 4 February 2020, to the U.S. Army Medical Center of Excellence. We received your FOIA request directly from the U.S. Army Freedom of Information Act Office/FOIA Liaison, at the Records Management and Declassification Agency (RMDA), 9301 Chapek Road, Building 1458, Ft Belvoir, VA 22060-5605 as a referral.

I have been assigned as your FOIA action officer and will be the individual processing your request. Please consider this an interim response as stated in your request which is; "This request concerns the use of animals in research, teaching etc. at the U.S. Army Medical Center of Excellence. For every Institutional Animal Care & Use Committee (IACUC) at the Center, we request the following: records seeking are specified in paragraphs 1a, 1b, 2a, and 2b." Attached to this email you will find your FOIA request as submitted to RMDA in its original form as received by this FOIA office for verification purposes.

Your FOIA case has been logged into the U.S. Army Freedom of Information Privacy Act Tracking System (FACTS). You may track the status of your FOIA case by using FOIA case control number FP-20-011365 at the RMDA website. Please use this link to access FACTS:
<https://www.foia.army.mil/facts/casestatus.aspx>.

The local MEDCoE FOIA case control number is FA-20-0007 and we request you use this number for any inquiries or requests for processing status with our FOIA office.

Sir, your FOIA case has been placed into our office queue and we will do our best to provide you with any responsive records. Please be advised that the four (4) items you have requested make your request a complex case; whereby I may be unable to respond within 20 business days with any responsive records. However, I will ensure I keep you updated on the case processing status by sending periodic emails to the address you have provided on the request.

If you have any questions or concerns about the processing of your FOIA case please don't hesitate to contact me directly at the phone number listed below or via email correspondence as well. Thank you.

V/r
Glenn W. Field
Records Manager, FOIA/PA/FMO/PCO

MEDCoE, G6 (ATMC-IM)
3630 Stanley Rd, Bldg 2840 Ste 0036
JBSA Fort Sam Houston TX 78234-6100
Office: (210) 221-6754/8156
DSN: 471-6754/8156

This action is administered under the Freedom of Information Act (FOIA)/Privacy Act (PA) Programs in compliance with 5 USC 552 (as amended), 32 CFR 518, DoD Directive 5400.7, and AR 25-55, and Department of Defense Directive (DoDD) 5400.11, May 8, 2007, Privacy Program, and DOD Regulation 5400.11-R, May 14, 2007, DOD Privacy Program and Army Regulation 340-21, the Army Privacy Program.

The information herein is For Official Use Only (FOUO) which must be protected under the Privacy Act of 1974, as amended. Unauthorized disclosure or misuse of this personal information may result in criminal and/or civil penalties.

CLASSIFICATION: UNCLASSIFIED



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163

January 16, 2019

Reference: Assurance **D16-00446 (A3752-01)**
Approval of Assurance

Kathleen Fogarty
Director
VA - Kansas City VA Medical Center
4801 E. Linwood Boulevard
Kansas City, MO 64128

Dear Dr. Fogarty,

I am pleased to inform you that the Office of Laboratory Animal Welfare (OLAW) reviewed and approved your institution's Animal Welfare Assurance (Assurance) that was submitted in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), revised 2015.

Your Assurance, identification number **D16-00446 (A3752-01)**, became effective on **January 16, 2019** and will expire on **January 31, 2023**. Please include the Assurance number on all correspondence to OLAW. A copy of the signed Assurance document is enclosed. The signature page provides verification of approval by OLAW and specifies the period during which your institution's Assurance is effective.

The Assurance is a key document in defining the relationship of your Institution with the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that an Annual Report to OLAW is required at least once every 12 months. Annual Reports for the previous calendar year are due by January 31st.

If I may be of any further assistance, please do not hesitate to contact me.

Sincerely,

1/16/2019

X Venita B. Thornton

Signed by: Venita B. Thornton -S
Venita B. Thornton, DVM, MPH
Senior Assurance Officer
Office of Laboratory Animal Welfare

Enclosure: As stated
cc: IACUC Chair

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
ANIMAL WELFARE ASSURANCE, A-3752-01

Animal Welfare Assurance for Domestic Institutions

I, Kathleen Fogarty as named Institutional Official for animal care and use at Kansas City Department of Veterans Affairs Medical Center, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, DHHS, and/or NSF (if applicable). This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

Building 15 (Medical Research Service)

Building 6 (Animal Research Facility)

All animals are housed in Building 6, and both buildings are located adjacent to one another.

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals (Guide)*.
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub award) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

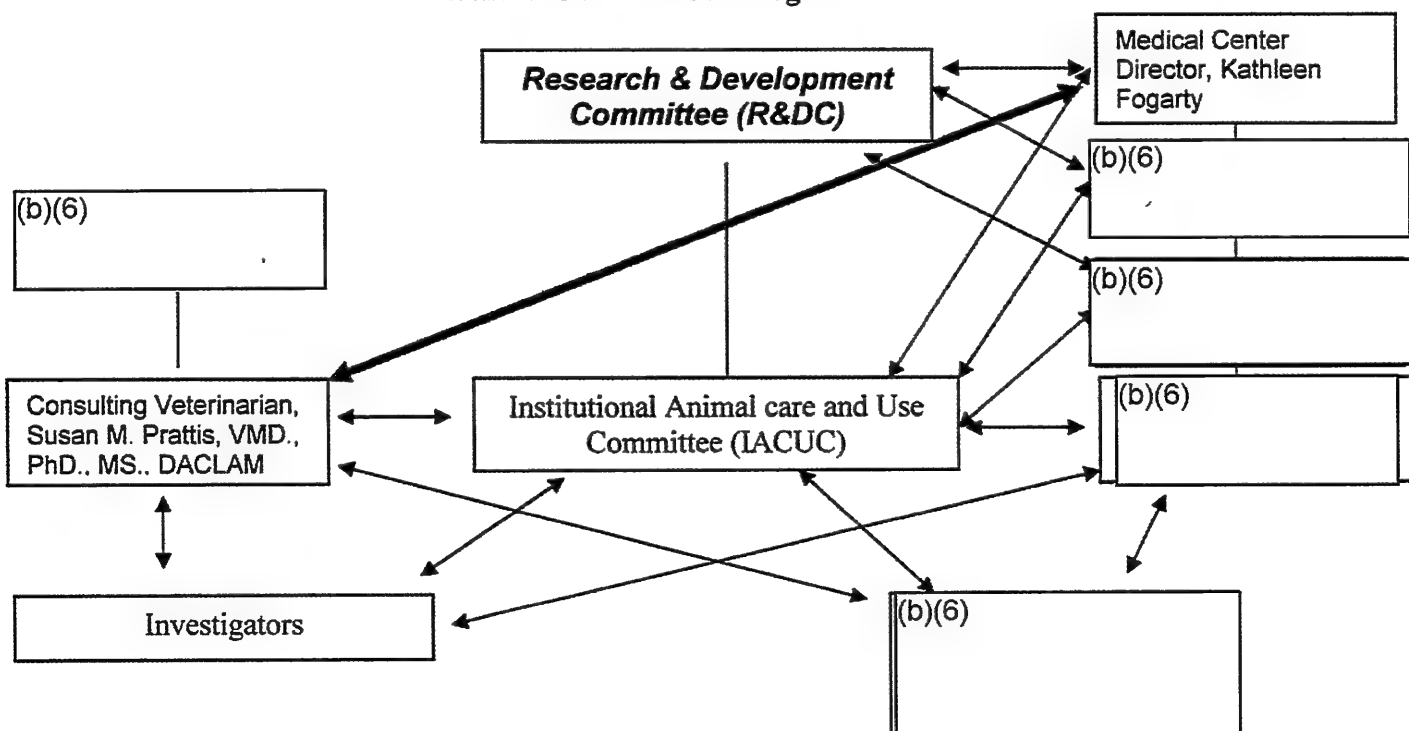
III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:
- *Institutional Official (IO)*: Kathleen Fogarty, Director of the Kansas City Veterans Affairs Medical Center (KC-VAMC) is the IO and bears ultimate responsibility for the KC-VAMC Animal Care and Use Program. Program direction and oversight is a shared

responsibility among the IO, Consulting Veterinarian, IACUC and Associate Chief of Staff for Research (ACOS).

- *Chief executive officer:* Dr. Ram Sharma, Ph.D., MHSA, Associate Chief of Staff for Research (ACOS for Research) is responsible for the health and well-being of animal resources and oversees all aspects of animal care and use, including supervision of personnel providing direct animal care.
- *Veterinarian:* Dr. Susan M. Prattis, VMD., PhD., MS., DACLAM serves as the Veterinary Medical Consultant and is responsible for the health and well-being of all animals involved in research and oversees all aspects of animal care and use. The Veterinary Medical Consultant has a direct line of communication and line of authority with the Institutional Official.
- *IACUC:* The IACUC is responsible for assessment and oversight of Program components and facilities. Dr. William Suo, M.D., Research Scientist serves as IACUC Chair. Miss Connie Wallace, IACUC Coordinator supports IACUC functions.
- *Animal facility management:* Mr. Kevin K. Byrd serves as Animal Research Facility (ARF) Manager with responsibility for managing ARF operations. Mr. Byrd reports directly to Dr. Sharma.

Organizational Diagram
Kansas City Veterans Affairs Medical Center
Animal Care and Use Program



- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

- 1) Susan M. Prattis, VMD, PhD., MS., DACLAM, serves as Veterinary Medical Consultant and spends approximately 2 hours on site each week; one hundred percent of Dr. Prattis's time on site is dedicated to the animal care and use program. Dr. Prattis is responsible for the health and well-being of all animals involved in research and oversees all aspects of animal care and use. Dr. Prattis has 37 years of experience as a veterinarian in the field of laboratory animal medicine. She holds an active US (IA, MA, NYS) and International Veterinary License from Kingdom of Denmark. She is a Diplomat of the American College of Laboratory Animal Medicine.

Authority: Dr. Prattis has *delegated* program authority and responsibility for the Institution's animal care and use program including access to all animals.

- 2) Allison L Bright, DVM serves as the backup veterinarian for the facility and spends approximately 2 hours on site each month; one hundred percent of Dr. Bright's time on site is dedicated to the animal care and use program. She has 18 months of experience and is currently a Clinical Veterinarian in Research with the University of Kansas Medical Center. Dr. Bright received her DVM from Kansas State University in May 2013.

Authority: Dr. Bright has *delegated* program authority and responsibility for the Institution's animal care and use program including access to all animals.

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b.

Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

Name	Degree	Title	Profession	Institutional Affiliation
(b)(6)				

- D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

- The KCVAMC-IACUC conducts a review of the Animal Care and Use Program at least once every six months. All members are invited to attend but a minimum of 3 members, two of which must be voting are required.
- The Guide for the Care and Use of Laboratory Animals, supplemented by the USDA Animal Welfare Act and Regulations where applicable, are the standards for evaluation.
- The KCVAMC IACUC uses the "VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities" checklist. *The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVM. All sections have references to PHS and The Guide.*
 - Part I Checklist, Section A Review of the Program: An administrative evaluation of all policies, plans, standard procedures and systems under which the institution fulfills its responsibilities.
 - Section I Institutional Policies and Responsibilities includes the following areas: (A) Shared Responsibilities; (B) General IACUC Functions; (C) Semiannual Evaluations of the Animal care and Sue Program; (D) Standard Operating Procedures; (E) Addressing Concerns about Animal Welfare; (F) Reporting to Oversight Entities; (G) Personnel Qualifications and Training; (H) Occupational Health and Safety Program (OHSP).
 - Section II Physical Plant – infrastructure and policies and procedures for maintenance and functionality.
 - Section III Operations Related to Animal Environment, Housing and Management includes the following areas: (A) Physical Environment; (B) Husbandry; (C) Animal Procurement and Transportation; (D) Preventive Medicine; (E) Waste Disposal; (F) Pest Control; (G) Medical Supplies; (H) Emergency, After Hours, Weekend, and Holiday Animal Care
 - Section IV Veterinary Medical Care include the following areas: (A) Role of the Veterinarian; (B) Surgery; (C) Pain, Analgesia, and Anesthesia; (D) Euthanasia
 - Section V Animal Care and Use Program Work Orders. Work order completed since the previous semiannual program evaluation and work order not yet completed.
- Subcommittees, appointed by the IACUC Chair and composed of no fewer than three members (two of which must be voting members), perform semiannual program evaluations using the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Checklists as a guide.
- Written subcommittee findings are reviewed during a convened IACUC meeting. Following discussion and any necessary revision, the report is voted on and signed by a majority of IACUC members.
- The signed report is forwarded to the IO. Ad hoc committees are formed to address recommended programmatic changes or identified deficiencies.
- The IACUC Coordinator is responsible for tracking progress made on pending items from semiannual evaluations. Progress is documented and reports are updated once all deficiencies have been corrected

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

- The KCVAMC-IACUC conducts a review of the Animal Care and Use Program and performs inspections of all animal holding and use areas at least once every six months. All members are invited to attend but a minimum of 3 members, two of which must be voting are required.
 - The Guide for the Care and Use of Laboratory Animals, supplemented by the USDA Animal Welfare Act and Regulations where applicable, are the standards for evaluation.
 - The KCVAMC IACUC uses the "VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities" checklist
 - Part I Checklist, Section B Inspection of the Facilities: Inspection of the Facilities focuses on a physical and visual evaluation of building, equipment, and the environment in which animals are maintained and utilized.
 - Section I Implementation of Institutional Policies, sections include (A) Performance of Work According to Protocol; (B) Addressing Concerns about Animal Welfare; (C) Occupational Health and Safety.
 - Section II Physical Plant – Sections include (A) General - HVAC; Power & Lighting, Noise Control and Environment Monitoring; (B) Facilities for Sanitation; (C) Storage Areas; (D) Facilities for Aseptic Surgery; (E) Special Facilities; (F) Ancillary Areas; (G) Security
 - Section III Animal Environment, Housing and Management – sections include Physical Environment; (B) Husbandry; (C) Animal Procurement and Transportation; (D) Preventive Medicine; (E) Waste Disposal; (F) Pest Control; (G) Medical Supplies; (H) Emergency, After Hours, Weekend and Holiday Care
 - Section IV Veterinary Medical Care – sections include General, Surgery, Pain Distress, Analgesia and Anesthesia, Euthanasia;
 - Teams of IACUC members, appointed by the chair and composed of no fewer than three members (two of which must be voting members), perform semiannual program evaluations using the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Checklists as a guide. Members may elect to participate in any facility inspection regardless of assignment.
 - Inspection reports categorize deficiencies as minor or significant and include a corrective action plan with completion dates and responsible parties. Inspection reports are reviewed during a convened IACUC meeting. Following discussion and any necessary revision, the report is voted on and signed by a majority of IACUC members. The signed report is presented /forwarded to the IO for his review and signature.
 - The IACUC Coordinator is responsible for tracking progress made on pending items from semiannual evaluations. Progress is documented and reports are updated once all deficiencies have been corrected.
- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:
- Written reports of IACUC semiannual evaluations are reviewed during a convened IACUC meeting. Following discussion and any necessary revision, reports are voted on and signed by a majority of IACUC members.

- The signed report, including a description of the nature and extent of this institution's adherence to the *Guide*, a list of IACUC-approved departures from the *PHS Policy* and the *Guide*, the reason for each departure, and any minority views is provided to the IO and the ACOS for Research. Additionally, the IO and the ACOS are informed, in writing, of non-compliance events, animal welfare concerns, and animal use statement (protocol) suspensions.
 - Inspection reports categorize deficiencies as minor or significant and include a corrective action plan with completion dates and responsible parties. Ad hoc committees are formed to address recommended programmatic changes or identified deficiencies. The IACUC Coordinator is responsible for tracking progress made on pending items from semiannual evaluations. Progress is documented and reports are updated once all deficiencies have been corrected.
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
- The philosophy of the Kansas City VA Medical Center is that it is a privilege to use animals in research and instruction, and the Medical Center is committed to protecting animal welfare. The Institutional Animal Care and Use Committee, Research Service staff, Animal Research Facility staff, and the Animal Welfare Assurance Program rely upon all who work with research animals at our VA to share this commitment. Thus, any time any Kansas City VA employee has concerns with respect to the animal care or use at Kansas City VA, they are encouraged to report the situation immediately. These concerns may include but are not limited to all aspects of the *Guide*.
 - Individuals may report their concerns by phone, in writing, or by fax or e-mail if confidentiality is not an issue. The person making the report is not required to provide his or her name. The Research Office will evaluate the situation with input from the Veterinary Medical Officer, attend to the health of the animals if necessary, and then complete a report form that is immediately forwarded to the IACUC. The IACUC will take appropriate action in a timely manner.
 - The procedures outlined below are designed to ensure that any individual can report a concern, anonymously if desired, without fear of reprisal. Signage is posted in the Animal Research Facility. Any concerns or deficiencies in the care and/or treatment of animal or any activities related to animal care that may be improper or inhumane should be reported. Concerns may be reported verbally, in writing or by email to any of the following:
 - To Investigator and/or direct supervisor
 - Veterinarian
 - Chair-Institutional Animal Care and Use Committee
 - Any IACUC member
 - Associate Chief of Staff for Research
 - Administrative Officer for Research
 - Any ARF Staff

Note: Anonymous reports may be submitted by interoffice mail addressed to "151-xxx (any of the titles above).
 - The anonymity of individuals reporting concerns will be maintained to the degree legally possible. No person shall be retaliated against as a result of voicing a concern.

The individual(s) against whom the allegations are made will be treated in a fair and professional manner throughout the investigation.

- In emergencies, the Consulting Veterinarian has been given authority to take necessary action to relieve animal suffering and address animal welfare issues. The concern and action taken by the Consulting Veterinarian will be reported to the IACUC Chair or designee by the end of the next regular business day. The Chair or designee will appoint an ad hoc subcommittee as described below.
- Within 72 hours of receipt of non-emergency concerns, the Chair or designee will appoint an ad hoc subcommittee. The subcommittee will be composed of no less than three IACUC members (two of which must be voting). The subcommittee will report its findings to the IACUC at the next scheduled or called meeting.
- After reviewing the facts surrounding the violation and after having given the investigator opportunity to present his/her case to the IACUC, the IACUC will take appropriate corrective action. This action may range from but is not limited to requiring more frequent inspections and/or monitoring, requiring additional training, placing the Principal Investigator on probation for a period of time, removing certification of certain individuals associated with the violation, to suspension of the approval of the Animal Component of Research Proposal (ACORP).
- The IACUC may suspend an activity or impose lesser corrective remedies if activities are not conducted in accordance with an approved ACORP or applicable provisions of the Animal Welfare Act, the *Guide*, this Assurance, or *PHS Policy* only after review of the matter at a convened meeting of a quorum of the IACUC and with the vote of a majority of the quorum present. A written summary of findings and actions is forwarded to the IO, the Principal Investigator and all other required parties. Animal activity suspension is further described in section III.D.10 below.

- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

- Written reports of IACUC semiannual program review and facility inspections are submitted to the IO following IACUC approval.
- Additionally, the IO is informed, in writing, of non-compliance events, animal welfare concerns, and Animal Use Statement (protocol) suspensions.
- The IO or his designee regularly attends IACUC meetings as an ex-officio member.
- The ACOS for Research meets regularly with the IO to discuss program needs and direction.

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

The IACUC convenes monthly to consider animal care and use related issues and protocols. An agenda is circulated to all committee members at least three days prior to the scheduled meeting. A list of all applications and proposals for the use of live vertebrate animals is included with the agenda. All new proposals for any use of animals undergo full IACUC review. Review of proposals is based on criteria including, but not limited to the following i) *Guide for the Care and Use of Laboratory Animals*; ii) American Veterinary Medical Association's Panel on Euthanasia (J. Am. Vet. Med. Assoc. 202: 229-249, 1993); iii) PHS Policy; iv) Animal Welfare Act; v) U.S. Government Principles; and vi) current standards of accepted veterinary practice

Initial Submission New Study

The ANIMAL COMPONENT OF RESEARCH PROTOCOL VERSION 4 is submitted to the IACUC Coordinator

Pre-Review

Veterinary Review - All new ACORPS must be sent to the Consulting Veterinarian for pre-review prior to submission to the IACUC. The Consulting Veterinarian assures appropriateness of described procedures, husbandry methods, drug selection and dose, pain and distress monitoring, and endpoint determination, and if the pain/distress category is appropriate based on IACUC and USDA guidance. The Consulting veterinarian will provide feedback to the investigator within 4 business days.

Administrative Review - IACUC Coordinator accepts the submission, assigns a study number, and performs a basic review to verify completion of all relevant sections and appendixes. If required, the coordinator contacts the PI to require completion of any missing information.

Safety Review - All new ACORPS are forwarded to the Safety Committee for review of bio-safety and radiation concerns.

IACUC Review

All ACORPs must be approved by the IACUC regardless of funding source. The IACUC uses Full Committee Review (FCR) for all new study submissions. No member may participate in the IACUC review or approval of a research project in which member has a conflict of interest except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

For all studies involving potential pain/distress, the IACUC requires an alternative search regardless of species. Additionally, all protocols must identify how pain and distress will be assessed and define specific endpoints.

Full Committee Review (FCR)

FCR occurs only at a convened meeting and a quorum is necessary for any business to be conducted by the IACUC. An IACUC member, hereafter referred to as the primary reviewer, appointed by the chair reviews the ACORP. All queries by the primary reviewer along with queries generated in the protocol pre-review are forwarded to the PI for resolution and ACORP modification. Approve, require modifications to secure approval, or approval withheld are the only allowed protocol dispositions for FCR. Protocol disposition is determined by majority vote of the quorum present. When modification is needed to secure approval, a quorum of members present at a convened meeting may decide to use Designated Member Review (DMR) provision by unanimous vote. If electing to use DMR, the IACUC Chairperson appoints two or more appropriately qualified IACUC members to serve as the designated reviewers. All members of IACUC have agreed, in writing, to this provision in advance. Any IACUC member at any time, may request to see the full ACORP and/or request FCR prior to approval.

Designated Member Review (DMR)

DMR provision is not used for initial review of any new study. DMR provision is only used (a) to review *Modifications Required to Secure Approval* after full committee review (FCR) or (b) for review of amendments/addendums that are not significant changes to an existing protocol (as indicated below under Submission of Amendments). The only allowed protocol

dispositions for DMR are Approved, Require Modifications to Secure Approval or referral to FCR.

DMR provision for "Modifications Required to Secure Approval" after FCR,

- When IACUC during FCR decides to use DMR provision for required modifications review to secure approval of the protocol, then the IACUC Chairperson in consensus with committee members appoints two appropriately qualified IACUC members (VA requirement of 2 members for DMR) to serve as the designated reviewers.
- The IACUC Coordinator sends required modifications request memo to Investigator. On receipt of all required modification documents from Investigator, IACUC Coordinator sends the memo and all modified documents (provided by Investigator) to designated reviewers for DMR by email at the same time.
- The designated reviewers are given three business days to complete their review of the required modifications of the identical version of the protocol. Both reviewers make their comments on the email and the IACUC Coordinator ensures that both reviewers have reviewed all documents and that both are unanimous in their decision regarding the outcome of the protocol review. If any designated reviewer request for additional modifications/clarifications of the protocol then the request of such modifications (when received by IACUC Coordinator) is sent to other reviewer via email to make him/her aware of and agree to the modification. In such case designated reviewers are provided an additional three business days to review the documents. When both designated reviewer agrees unanimously in their decisions about required modifications

DMR of an Amendment/Addendum,

- The IACUC Coordinator sends all documents received with the amendment/addendum, request to all IACUC voting members via email. Committee members are directed to reply with any comments or requests for full committee review within 3 business days. If any additional documents are requested during that time – all committee members are sent the additional requested information to ensure that all members are reviewing the identical version of the documents.
- If no member requests full committee review within 3 business days, then the IACUC Chairperson and/or veterinarian determines if the submitted amendment/addendum meets the conditions for DMR. If electing to use DMR, the IACUC Chairperson appoints two or more appropriately qualified IACUC members (VA requirement of 2 members for DMR) to serve as the designated reviewers.
- Designated reviewers are requested to make their determination for modifications and/or approval on the submitted amendment/addendum and reply to the IACUC Coordinator by email. The IACUC Coordinator ensures that both reviewers are aware of and agree with the requested modifications and/or approval communication by any one of the reviewer. Both reviewers be unanimous in their decision regarding the outcome of amendment/addendum review.

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Submission of Amendments

Changes or modifications to approved protocols, hereafter referred to as amendments for animal use must be reviewed and approved by the IACUC prior to being implemented by investigators.

- For significant changes to existing protocols, a new ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP) VERSION 4 is submitted to the IACUC Coordinator. FCR is required for new ACORP submissions.

Examples of significant protocol changes to an existing protocol that require a new ACORP and FCR are as follows:

- Revision of the hypothesis that will be tested or change of objectives;
 - Increases in the anticipated level of pain and distress for a proposed procedure relative to the originally-approved procedure;
 - Use of a different animal species;
 - Substitution of a survival surgery procedure for a non-survival procedure, or change from non-survival to survival;
 - Addition of multi-step surgeries;
 - Addition of new hazardous compounds for a protocol that previously did not use hazardous agents;
 - Change of principal investigator
 - Changes that impact personnel safety
- For amendments/addendums that are not significant changes to an existing protocol, an ADDENDUM form can be completed and submitted to the IACUC coordinator. DMR can be requested for ADDENDUMS.

Examples of amendment/addendum requests to an existing protocol that can be reviewed by DMR:

- Requesting more animals to use in the same procedures or to test in the same model;
- Adding additional compounds to test;
- Modifying an existing surgical procedure;
- changing the type or dosing of analgesia,
- Addition of additional blood collections to an existing protocol
- Change in source of animals
- Addition of noninvasive procedures
- Changes which result in a decrease of invasive procedures
- Addition or deletion of personnel (excluding the PI)

Pre-Review

Procedures are the same as stated in Section III.D.6

IACUC Review

Procedures are the same as stated in Section III.D.6

Full Committee Review (FCR)

Procedures are the same as stated in Section III.D.6

Designated Member Review (DMR)

Procedures are the same as stated in Section III.D.6

- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications

required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The IACUC Chair notifies investigators and the IO in writing of the committee's decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC withholds approval of an activity, the committee includes in its written notification to the investigator a statement of the reasons for the decision and provides the investigator an opportunity to respond in writing. All decision regarding protocol approval, protocol modifications, and annual review of protocols are recorded in the monthly IACUC agenda and minutes, which are circulated to the IACUC and the IO (via the Research and Development Committee).

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

The IACUC reviews all ongoing animal protocols at least annually. Review is conducted to assure continued compliance with applicable laws, regulations and policies. All ACORPs are approved for a three-year period regardless of fund source. Continuation of work beyond the third year requires IACUC approval of a de novo ACORP submission. De novo submissions are reviewed and approved as described in Part III.D.6 above. An annual renewal application must be submitted at least 45 days prior to the first and second approval anniversary of all ACORPS.

Continuing review of previously approved ongoing activities will be conducted at yearly intervals, or more frequently, as determined by the IACUC. A one-page renewal form for continuing review is provided to the investigator by the IACUC, via the Research Office, requesting information regarding the status of the project (active or inactive) and whether there are changes to the project. If no significant changes are noted by the individual submitting the renewal, the form will be reviewed by the Research Office and then presented to the IACUC as an agenda item at the next convened meeting. Activities with modifications will be noted for the IACUC. All projects will be subject to a de novo review at least once every three years

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend an activity that it previously approved if it determines activities are not conducted in accordance with an approved ACORP or applicable provisions of the Animal Welfare Act, the *Guide*, this Assurance, or *PHS Policy* only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the IO and the ACOS in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with full explanation to OLAW.

- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

- 1) Control and Prevention Strategies:

Prevention strategies for the KCVAMC Occupational Health Program is a coordinated effort between the Employee Health Service, Safety Office and the Animal Care and Use Program. New employees joining the Research Service at the KCVAMC are required to indicate if their job responsibilities include work and/or exposure with laboratory animals, if so, then they are required to receive training on risks involved with animal exposure and/or interactions including information about zoonosis. In addition, all personnel who work in our laboratory animal facility or on animal research experiments are required to take the web-based infection control course and training on fire and chemical safety

All Animal Facility staff and researchers who use the facility undergo a pre-employment physical examination including immunizations for relevant pathogens, TB test, and rabies titer through the KCVAMC Employee Health Service to record and maintain health history to ensure that animal work does not pose unnecessary risks. In addition, annual health evaluations are also conducted and reviewed by medically trained personnel meeting federal, state and local HIPAA regulations.

2) Hazard identification and risk assessment:

Kansas City VA Medical Center has established programs for hazard identification. These programs are designed to communicate hazards in the workplace. Hazards include chemical, biological, and physical agents. Detailed information regarding laboratory safety and chemical, biological, and physical agent hazards can be found in the "Kansas City VA Laboratory Safety Manual and Chemical Hygiene Plan"

In addition, all animal protocols are also reviewed by our Institutional Biosafety/ Research Safety Committee to identify associated hazards and risk levels based upon by potential for exposure to blood-borne and airborne pathogens, physical agents, or chemicals and the outlined procedures and specific mitigation practices for the personnel.

Both the Facility Environment of Care Committee and the Research Safety Committee conduct semi-annual inspections of all lab areas to identify associate hazards. When hazards are identified, corrective action procedures are communicated to the ACOS for Research and lab personnel.

Facilities, equipment, and monitoring

Hazardous materials are contained within the study environment and animal housing area through a combination of husbandry practices, engineering controls, administrative controls, and PPE use. Husbandry practices to ensure personnel safety include use of individual ventilated caging system for rodents and use of primary containment devices such as biological safety cabinets, chemical fume hoods, and cage change stations. Administrative controls to reduce inadvertent exposure include institutional policies, facility access restriction, IACUC SOP, Laboratory Safety Manual and Chemical Hygiene Plan and required employee trainings. In addition, Personal Protective Equipment (PPE) is provided to individuals based on work location and scope of work and may include disposable outerwear, eye protection, face protection, respiratory protection, gloves and footwear.

Personal hygiene

A high standard of personal hygiene is essential to the successful operation of the program. Hand washing and/or showering is encouraged. Smoking is prohibited in all areas of the animal facility.

Sinks, along with soap and hand towels are available throughout the Animal Research Facility. Personnel must remove PPE prior to exiting animal facilities. Eating and drinking are permitted only in rooms in which animals are not housed and laboratory chemicals are not used.

Animal experimentation involving hazards

All research personnel with job responsibilities requiring exposure to animals, hazardous materials, etc., are monitored by Kansas City VA Medical Center according to OSHA regulations. All

employees are assessed for risk related to their job assignments; training is provided relative to that risk. Risk levels are determined by potential for exposure to blood, blood-borne pathogens, physical agents and/or chemicals. Risk assessment also includes consideration of pregnancy, illness or immunocompromised.

The Research Safety Committee oversees the use of biological, chemical, and radiological hazards. No hazardous materials may be used in animal research without the Research Safety Committee review and approval. The Research Safety Committee approval is required before final approval is given.

Husbandry practices to ensure personnel safety include use of micro-isolator caging for rodents and biosafety cabinets for cage manipulation of rodents exposed to biohazards. Engineering controls used to prevent and minimize personnel hazard exposure include negative pressure containment, anesthetic waste gas scavenging, and use of primary containment devices including: biological safety cabinets, chemical fume hoods, and cage change stations.

Protective clothing will be worn to enter all animal housing areas and when working with animals in procedures areas. All animal care staff are provided with surgical scrubs to wear during work hours. Supply of these scrubs is sufficient for several clothes changes per day. Scrubs are laundered by the Kansas City VAMC. Other protective gear provided includes disposable outerwear, rubber aprons, and boots, disposable shoe covers, masks, and head covers, latex gloves, rubber gloves, safety glasses, surgical gowns. The animal research facility has shower and hand-washing facilities in the men's rest room. A shower/locker facility for female employees is available adjacent to the animal facility.

Medical evaluation and preventive medicine for personnel

All individuals with direct animal contact and noncontact personnel that enter animal facilities are included in the KCVAMC Occupational Health Program (OHP). Personnel enroll in the OHP undergo a health assessment. The assessment flags individuals who report health issues that may be aggravated by work in an animal facility for consultation with a health professional. Individuals flagged as "pending medical review" are contacted and offered an opportunity for follow-up consultation with a health professional.

Employees exposed to hazardous agents; infectious or otherwise, are instructed to report the incident to their supervisor and then to Employee Health Service. On-the-job injuries are given priority either by Employee Health Service or the VA Medical Center Emergency Room.

Personnel are required to notify their immediate supervisor of all work place injuries. The supervisor must file a VA Form 2162 when they become aware of a worker's work-related injury or illness, completing VA Form 2162 within 5 days after notification by an employee who reports the incident and closing VA Form 2162 in ASISTS when the incident investigation is complete.

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

[Complete the Facility and Species Inventory table provided (see Part X.).

Note: list common names for animal species, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog.

Note: animal areas (buildings/rooms) may be represented by a number or symbol in this submission to OLAW.]

- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

Training for all Kansas City VAMC personnel who use animals or are IACUC members involves a two-fold approach. First, new employees are requested to indicate whether or not work involves care and use of animals in research and whether they will be an IACUC member. If so, these employees are required to receive orientation by the research office. This orientation is governed by standard operating procedures on training (SOP-Animal Care and Use Training Program). New employees who will work with animal protocols must review a written document on regulations governing animal care and use, humane care and use, zoonosis, allergy, and other health issues related to animal care and use. They are required to complete the CITI Program modules on Animal Training and review the Guide for the Care and Use of Laboratory Animals and the Standard Operating Procedures for the program. Training includes instruction aimed at 1) Reduction—limiting or minimizing the number of animals used in research; 2) Refinement—limiting or minimizing animal pain or distress; and 3) Replacement—whenever possible, replacing the use of animals in research protocols with less sentient species. They then must sign an affirmation of completion (in the Scope of Practice), which serves as documentation of their initial training.

New IACUC members receive an orientation provided by the IACUC Chair, IACUC Coordinator and ACOS for Research Service. The orientation consists of the following:

- Discussion of IACUC Member Responsibilities, including the Protocol Review and Laboratory Inspection,
- IACUC Full Committee review and the Designated Review process and new members are told that any member could read and evaluate any protocol even if not assigned to do so.
- Discussion of the current Animal Use Protocol Form (ACORP) and what the investigators are expected to provide in each section. Attention is given to the importance of the correct use of the literature search, complete description of animal handling procedures, issues of pain and distress, justification of the numbers of animals needed, and the justification of the use of animals.
- Links to the following
 1. The PHS Policy
 2. The Guide
 3. USDA/ APHIS website)
 4. The AVMA Guidelines on Euthanasia
 5. Protocol Review Checklist
 6. Blank Protocol Review Form
 7. Laboratory Inspection Checklist
 8. Program Review Checklist
 9. The Whistleblower Policy
 10. Institutional Animal Care and Use Committee SOP.
 11. Citi Program web site to take the Essentials for IACUC Members training
- Continued education/training is also provided at least semi-annually to all IACUC Members. Topics regarding IACUC review process are discussed.
- All IACUC members are encouraged to attend IACUC Conferences and/or workshops

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at

least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

- (1) This Institution is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) &. As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Kathleen Fogarty *Medical Center Director*.
 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 3. Any change in the IACUC membership
 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Kathleen Fogarty *Medical Center Director*..
 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 1. Any serious or continuing noncompliance with the PHS Policy
 2. Any serious deviations from the provisions of the *Guide*
 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval**A. Authorized Institutional Official**

Name: Kathleen R. Fogarty

Title: Director

Name of Institution: Department of Veterans Affairs Medical center

Address: (street, city, state, country, postal code)

4801 E. Linwood boulevard, Kansas City, MO 64128

(b)(6)

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature: 

Date: 12/28/2018

B. PHS Approving Official (to be completed by OLAW)

(b)(6)

(b)(6)

VIII. Membership of the IACUC

Date: 9-25-2018
Name of Institution: Kansas City VA Medical Center
Assurance Number: A-3752-01

IACUC Chairperson

Name*: William Suo

Title*: Medical Research Scientist

Degree/Credentials*: M.D.

(b)(6)

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
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VOTING MEMBERS

(b)(6)

(b)(6)

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1

(b)(6)

Contact #2

(b)(6)

X. Facility and Species Inventory

[illegible]

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year: 2019

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

REGISTRATION NUMBER: **RN: 43-V-0002, CN:1374**

Customer Number:

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include ZIP Code)

Kansas City VAMC (589) 4801 E Linwood Blvd Kc

Telephone: **(816) 922-2757**

**ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)**

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
					n/a
13. Other Animals					0
					n/a
					n/a
					n/a

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (L.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR L.O.

David B. Isaacks 172543 Digitally signed by David B. Isaacks 172543
Date: 2020.04.30 08:35:23 -0500

NAME AND TITLE OF C.E.O. OR L.O. (Type or Print)

David Isaacks, FACHE Director

DATE SIGNED

4/30/2020

APHIS FORM 7023
JUL 2013

APHIS Form 7023 Site Addendum for FY:

Registration Number:

Customer ID Number:

Facility Business Address Information:

Telephone:

Facilities Site(s) Address Information:

Site Code(s):



DEPARTMENT OF THE NAVY
NAVAL MEDICAL FORCES PACIFIC
4170 NORMAN SCOTT ROAD
SAN DIEGO, CA 92136-5501

IN REPLY REFER TO:

5720

Ser 00L/0059

7 Feb 20

Mr. Russ Kick
333 Washington Street Suite 850
Boston, MA 02108

REF: DON-NAVY-2020-003045

Dear Mr Kick:

Thank you for your Freedom of Information Act (FOIA) request dated December 23, 2019 and received in our office on December 31, 2019. Your request was for specifically for "1a) According to The Guide for the Care and Use of Laboratory Animals (The Guide), 8th edition, all entities must have a system in place for anyone (insiders or members of the public) to report concerns regarding animal welfare at a facility. These reports are either made directly to the IACUC Chair or a designated representative, or they eventually are routed to the IACUC Chair/representative. We request all such reported concerns received by the Chair since January 1, 2019. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.) 1b) Further, for all such reported concerns deemed supported, we request the notification sent to the Institutional Official. The time frame is January 1, 2019, to present. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.) 2a) Per The Guide, all entities must have a system in place for investigators to notify the IACUC and/or attending veterinarian of adverse events, unexpected or unanticipated outcomes, violations of protocols, and other incidents involving animal welfare that occur during their studies/experiments. We request all such notifications received by the IACUC or AV since January 1, 2019. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.) 2b) Further, we request all notifications sent to the Institutional Official regarding these reported incidents. The time frame is January 1, 2019, to present."

Since we must coordinate and consult with another agency or another Navy activity, we are availing ourselves of the 10 working day extension of response time provided in the Department of the Navy FOIA regulations (32 CFR §701.8(g)(2)).

We will send a final reply to you on or before February 17, 2020.

5720
Ser 00L/0059
7 Feb 20

If you have any questions regarding our response to your request, please contact the undersigned, Commander Edward B. O'Brien, JAGC, USN, Staff Judge Advocate. He can be reached at edward.b.obrien.mil@mail.mil.

Sincerely,



E. B. O'BRIEN
Commander, U.S. Navy

By direction
of the Commander



DEPARTMENT OF THE NAVY
NAVAL MEDICAL FORCES PACIFIC
4170 NORMAN SCOTT ROAD
SAN DIEGO, CA 92136-5501

IN REPLY REFER TO:

5720

Ser 00L/0078

18 Feb 20

Mr. Russ Kick
333 Washington Street Suite 850
Boston, MA 02108

Dear Mr Kick:

This further responds to your Freedom of Information Act (FOIA) request of December 23, 2019. Your request was received by this office on December 31, 2019. Your request was for specifically for "1a) According to The Guide for the Care and Use of Laboratory Animals (The Guide), 8th edition, all entities must have a system in place for anyone (insiders or members of the public) to report concerns regarding animal welfare at a facility. These reports are either made directly to the IACUC Chair or a designated representative, or they eventually are routed to the IACUC Chair/representative. We request all such reported concerns received by the Chair since January 1, 2019. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.) 1b) Further, for all such reported concerns deemed supported, we request the notification sent to the Institutional Official. The time frame is January 1, 2019, to present. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.) 2a) Per The Guide, all entities must have a system in place for investigators to notify the IACUC and/or attending veterinarian of adverse events, unexpected or unanticipated outcomes, violations of protocols, and other incidents involving animal welfare that occur during their studies/experiments. We request all such notifications received by the IACUC or AV since January 1, 2019. (This would encompass all appendices, annexes, attachments, and accompanying documents, including photos and videos in their original formats and resolution.) 2b) Further, we request all notifications sent to the Institutional Official regarding these reported incidents. The time frame is January 1, 2019, to present." Your request was assigned local Case File Number 014-20.

The releasable records responsive to your request are provided in enclosure (1). Our review of enclosure (1) revealed that the records contain personal identifiers (such as names of third parties), the release of which would constitute an unwarranted invasion of personal privacy. Accordingly, we must partially deny your request and redact (withhold) this information pursuant to FOIA Exemption 5 United States Code §552(b)(6). In addition, our review of enclosure (1) revealed that the responsive records contained information concerning personnel "in overseas, sensitive, or routinely deployable units." Accordingly, we must partially deny your request and redact (withhold) this information pursuant to FOIA Exemption 5 United States Code §552(b)(3).

5720
Ser 00L/ 0078
18 Feb 20

There were no assessable fees associated with the processing of your FOIA request.

This partial denial of your request is made on behalf of Commander, Naval Medical Forces Pacific (NAVMEDFORPAC), as an Initial Denial Authority for records under the FOIA. You may appeal this denial, in writing, to the Judge Advocate General of the Navy (Code 14), 1322 Patterson Avenue SE, Suite 3000, Washington Navy Yard, DC 20374-5066.

Your appeal must be postmarked within 90 days from the date of this letter to be considered. A rational statement as to why your appeal should be granted along with a copy of this letter and any supporting documentation should be attached as well. The appeal letter and envelope containing your appeal should bear the notation, "Freedom of Information Act Appeal".

For this determination, you have the right to seek dispute resolution services from the DoD Navy Component FOIA Public Liaison, Mr. Christopher Julka, at (703) 697-0031, at Christopher.a.julka@navy.mil, or the Office of Government Informational Services (OGIS) at <https://www.archives.gov/ogis/about-ogis/contact-information>.

If you have any questions regarding our response to your request, please contact the undersigned, Commander Edward B. O'Brien, JAGC, USN, Staff Judge Advocate. He can be reached at edward.b.obrien.mil@mail.mil.

Sincerely,



E. B. O'BRIEN
Commander, U.S. Navy
By direction
of the Commander

Enclosure:
Responsive Documents (eight pages)



DEPARTMENT OF THE NAVY
Memorandum

Report of Adverse Event

(b) (3) (B)(b) (3) (B)

DATE: 27 June 2019

FROM: **(b) (3) [Title 10 USC 130b] (b) (6)**

DEPARTMENT: Bacteriology

THROUGH: **(b) (3) [Title 10 USC 130b] (b) (6)** Alternate Attending Veterinarian

TO: **(b) (3) [Title 10 USC 130b], (b) (6)** Chair, Institutional Animal Care and Use Committee

SUBJ: ADVERSE EVENT TO PROTOCOL **(b) (3) (A) "EVALUATION OF MULTIVALEN
SHIGELLA VACCINE CANDIDATES IN THE AOTUS NANCYMAAE MODEL"**

1. Date event occurred: 27 June 2019
2. Date Identified: 27 June 2019
3. - Provide a detailed description of the event:

On 27 June 2019, an initial report of the death of an *Aotus nancymaae* **(b) (3) (B)** enrolled in IACUC protocol **(b) (3) (B)** "Evaluation of multivalent *Shigella* vaccine candidates in the *Aotus nancymaae* model" was reported by **(b) (3) (B)**. The monkey was challenged on 25 June with *S. flexneri* 2a strain 2457T at an inoculum dose of 1×10^{11} cfu and was part of the PBS control group.

One day post challenge (26 June), several monkeys on this protocol were found (by investigator and veterinary staff) to be showing varying degrees of unexpected severe illness. Evaluations of the animals were performed, and consultations were made between the AV, the investigator's staff, and the veterinary staff.

A total of 5 monkeys presented clear symptoms of the disease (bloody vomitus and diarrhea), and the determination was made to treat those animals based on clinical signs and/or protocol endpoints. All 5 animals received Enrofloxacin at doses listed in the protocol; 2 animals that appeared the most ill were also provided with oral electrolytes.

DEPARTMENT OF THE NAVY
Memorandum

Although ill (b) (3) (B) did not appear to be one of the most severely affected, and this animal was provided with antibiotics only. All monkeys on the study were monitored throughout the day on 26 June. None of the animals on the project displayed obvious worsening of symptoms when they were last evaluated by the Attending Veterinarian at 2115 hours; however, monkey (b) (3) (B) was found dead in the morning on 27 June 2019 (2 days post-challenge). Necropsy showed signs of upper gastrointestinal (stomach) hemorrhage and hemorrhage present throughout the entire duodenum and jejunum (most prominently in the distal 1/3). Histopathology is pending.

4. Explain the factors or causes that led to this event:

At this point in time, it is not possible to determine the primary cause of this unexpected death. Histopathology may shed some light on the pathogenic process. The acute nature of the death appears to be related to the pathogenicity of the experimental infection, as reported in the study (b) (3) (B).

In retrospect, the Attending Veterinarian believes a more conservative provision of oral electrolyte solution to all animals that received antibiotic therapy, despite whether they were reported to be eating or drinking, would have been appropriate. Dehydration was likely to have been at least one part of the cascade of pathologic processes in this animal.

5. Describe corrective actions already taken to address the event. Attach supporting documentation as needed:

- Although unexpected, once severe illness was identified in several monkeys, all animals on this project were monitored closely throughout the day and again at 2115 by veterinary staff and/or investigators. Treatment was initiated based on clinical signs and protocol endpoints.

6. Describe the plan for future corrective measures or procedural changes to prevent future events of this kind:

After a more thorough evaluation of the data, the investigators and veterinary staff will discuss refinement of this model with our co-investigators/collaborators. Possible changes include, but are not limited to reduction of the inoculum dose of this particular strain of *S. flexneri*; using a different strain of *Shigella* for challenge; and altering some of the animal model procedures; in order to mitigate future incidents. A retrospective analysis of recent *S. flexneri* studies will be performed to better identify risks associated with this animal model to re-evaluate endpoints and determine courses of action to better protect the well-being of the animals.

DEPARTMENT OF THE NAVY
Memorandum

These discussions will be aimed at decreasing adverse effects and should lead to the most appropriate course of action based on collaborative analysis. We will also continue to report any future adverse events to IACUC and re-evaluate the model and methods based on such outcomes.

Additionally, the Attending Veterinarian and veterinary staff will ensure that animals removed from a study because of illness are provided with oral fluid supplementation in a more conservative nature, recognizing that these small NHPs hide overt signs of illness and have a relatively high water turnover rate that cause them to become dehydrated rapidly (especially when otherwise compromised by disease).

b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

Date: July 1, 2019
Principal Investigator

The signature below certifies that this report was reviewed by the NAMRU-6 Attending Veterinarian or alternate.

b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

Date: July 1, 2019
Alternate Attending Veterinarian

From:
To:
Cc:

b(3)[Title 10 USC 130b], (b) (6)

Subject:
Date:

Re: NAMRU-6, Adverse event
Sunday, June 30, 2019 5:36:15 PM

b(3)[Title 10 USC 130b], (b) (6)

I appreciate everyone's efforts here. I concur that it is best to notify AAALAC with the complete report.

This is unfortunate. Thank you for keeping me informed. Let me know if the situation changes or if you need anything from me.

V/r,
CO

From: b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

Date: Friday, June 28, 2019 at 4:26:23 PM

To: b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

Cc: b(3)[Title 10 USC 130b], (b) (6) b(3)[Title 10 USC 130b], (b) (6)

b(3)[Title 10 USC 130b], (b) (6)

b(3)[Title 10 USC 130b], (b) (6)
Subject: FW: NAMRU-6, Adverse event

Sir,

FYSA: I just reported an adverse event (unexpected animal death) to BUMED.

It's been a busy crazy week in Vet Services; we challenged 40 monkeys with Shigella on Wednesday, and we had a large number of sick monkeys on Thursday and Friday. One animal died unexpectedly during the night on Wednesday, but all the rest appear to be in recovery phase now.

From a regulatory perspective, we are required to do two things:

1. DODI 3216.01 says to "notify Component oversight office in 5 working days." We notified them in 2 days.
2. AAALAC says to "notify AAALAC promptly." I have recommended to b(3)[Title 10 USC 130b], (b) (6) that we wait to notify AAALAC until the report is completed. A draft has been written, and it is being circulated for signature now. I would suspect that by the end of next week, it can be packaged and submitted to AAALAC. I don't anticipate that they will have concerns about how we have addressed this.

This adverse event, while unexpected, is not particularly notable from a regulatory standpoint. Science happens, and we don't yet know why this bacteria seemed to hit these monkeys so hard. We work with our investigators to figure it out and drive on.

Standing by for questions.
V/R,

b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
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b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

Email: b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

-----Original Message-----

From: b(3)[Title 10 USC 130b], (b) (6)

Sent: Friday, June 28, 2019 3:48 PM

To: b(3)[Title 10 USC 130b], (b) (6) b(3)[Title 10 USC 130b], (b) (6)

b(3)[Title 10 USC 130b], (b) (6)

Subject: NAMRU-6, Adverse event

Importance: High

(b) (6)

(b) is out today from the IACUC office, so I am assisting by doing the initial notification about an adverse event in our ACUP. We had an unexpected death of an animal on an experimental protocol sometime during the night of 26 June. This animal was experimentally challenged with Shigella as per our IACUC approved protocol, and we had a number of animals that were significantly (and unexpectedly) ill approximately 24 hours after challenge, which occurred on 25 June.

All other 39 animals on the study appear to be now recovering. A number of animals were removed from the study and treated with antibiotics between 24-48 hours post-challenge, based on reaching of endpoint criteria. A necropsy of the NHP that died was performed; histopathology is pending. The PI and his collaborators will be working to determine if there is a strain-specific aspect to the virulence of this inoculum, or perhaps whether it is a dose issue that caused the pathogenicity of the microbe. They are planning to report to the IACUC as they develop their conclusions.

A formal report is being prepared; please expect submission of that report to you sometime in the coming days. I will be travelling out of the country for a period, so (b) (6) will serve as Attending Vet in my absence. Note: I will be monitoring emails, but I will likely have very limited access so please anticipate delays in my reply.

Thanks so much!

b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)
b(3)[Title 10 USC 130b], (b) (6)

b(3)[Title 10 USC 130b], (b) (6)
Email: b(3)[Title 10 USC 130b], (b) (6)



DEPARTMENT OF THE NAVY

Memorandum

DATE: 19 July 2019

FROM: [b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6) Chair, Institutional Animal Care and Use Committee

TO: [b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6)

THROUGH: [b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6) Alternate Attending Veterinarian

SUBJECT: IACUC REVIEW OF REPORT OF ANIMAL DEATH IN ANIMAL USE [b(3)] [Title 10 USC 130b]
EVALUATION OF MULTIVALENT SHIGELLA VACCINE CANDIDATES IN THE AOTUS NANCYMAAE MODEL."

1. This letter is to inform you that the IACUC received and reviewed your voluntary report of the adverse event dated 27 June 2019.
2. Upon review of the circumstances leading up to the incident, IACUC agrees with your proposal to discuss with co-investigators/collaborators possible changes and refinement of this model. Possible changes include (but are not limited to) reduction of the inoculum dose, using a different strain of *Shigella*, and altering some of the animal procedures in order to mitigate future incidents.
3. Following your analysis and decision on a final course of action, please report your conclusions to the IACUC. We appreciate your candor in addressing these concerns and urge you to continue to report any future adverse events to IACUC and to re-evaluate the model and methods based on such outcomes.
4. Please do not hesitate to contact me if you require more information.

[b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6)
[b(3)] [Title 10 USC 130b], (b) (6)

IACUC CHAIR

Copy to
CO/IO
Attending Veterinarian
Protocol File

MEMORANDUM FOR: Chair, Institutional Care and Use Committee, 711 HPW Fort Sam Houston

THRU: (b) (6), Attending Veterinarian

SUBJECT: Adverse Event Report Form

Protocol #: (b) (6) Title 10 USC 130b (b) (6) Title 10 USC 130b Evaluating and Comparing the Regenerative Potential of Different Stem/Multiprogenitor Cell Types Seeded on a Novel Shape Memory Polymer Scaffold for Craniomaxillofacial Critical Size Bone Defects in a homozygous RNU (Crl:NIH-Foxn1 ^{rmu}) rat (<i>rattus norvegicus</i>)	PI Name: (b) (6)
Location of Adverse Event: (b) (6) Title 10 USC 130b (b) (6) Title 10 USC 130b	Species of Animal: Rats
Date/Time of Finding: 3/8/2019 11:00	
<p>Nature of Event – Please describe what happened: Rat number (b) (6) Title 10 USC 130b (b) (6) Title 10 USC 130b had his cage changed on 3/6/2019. However, prior to transfer to the clean cage, the technician inadvertently failed to add food to the cage. This was discovered two days later on 3/8/2019. The daily observation worksheet indicated that all cages in the room had been checked, including feed, and no issues were noted. Upon discovery, the rat was examined cageside and appeared bright, alert, and responsive. He was adequately hydrated. The rat lost 35 grams during the ~48 hours without feed. He will be monitored over the next few days and weighed on Monday (3/11/19) to ensure weight loss is resolved.</p> <p>Solution strategy: All animal care personnel will receive additional training on cage-changing and daily animal observation procedures to ensure this incident does not reoccur. Additionally, a checklist for cage changing will be added to ensure that the technician that changes the cages that day verified that food and water is in the cage.</p>	
Person Reporting Event: (b) (6)	
Date of Report: 3/8/2019	



TULSAZOO
MANAGEMENT, INC.

Inspiring passion
for wildlife in every
guest, every day.

July 8, 2019

Russ Kick
PO Box 36914
Tucson, AZ 85740

Via Certified Mail

Dear Mr. Kick:

Per your request, I have enclosed all "necropsies of Tulsa Zoo animals performed during 2018 and thus far in 2019".

Sincerely,

Joe Barkowski
Vice President Animal Conservation & Science
Tulsa Zoo Management, Inc.
jbarkowski@tulsazoo.org

Enclosure (1)

6421 E 36th Street N
Tulsa, OK 74115-2102

Tel: 918.669.6600

Fax: 918.669.6610

www.tulsazoo.org

ACCREDITED BY THE
**ASSOCIATION
OF ZOOS &
AQUARIUMS**

Species	Local ID	Sex	Age	Date of Death	Euthanized	Cause of death/reason for euthanasia	Other notes
Red-billed firefinch	17873	1.0	10M6D	1/1/2018	N	Undetermined	
Red-billed firefinch	17430	1.0	2Y8M30D	1/1/2018	N	Hepatic amyloidosis	
Malanilla turtle	12056	1.0	27Y3M24D	1/6/2018	N	Fungal pneumonia	
Tammar Wallaby	16375	1.0	7Y3M18D	1/15/2018	N	Histoplasmosis	
Sebas short tailed bat	14700	0.1	Geriatric	1/15/2018	N	Geriatric decline	
Fairy bluebird	13772	1.0	17Y8M14D	1/15/2018	N	Geriatric, mycobacterial pneumonia and other chronic disease processes	
Red-billed firefinch	17826	0.1	1Y4M7D	1/16/2018	N	Head trauma	
Tentacled Snake	17314R	1.0	Adult	1/16/2018	N	Unknown	too autolyzed for postmortem exam
Tentacled Snake	17314R	1.0	Adult	1/17/2018	N	Unknown	too autolyzed for postmortem exam
Tentacled Snake	17314R	1.0	Adult	1/17/2018	N	Undetermined, multifactorial	
White Faced Saki Monkey	14074	1.0	24Y5M0D	1/18/2018	N	Chronic renal disease/geriatric decline	
Sebas short tailed bat	14700	0.1	Geriatric	1/18/2018	N	Geriatric decline	
Blue capped Cordon-bleu	18002	0.1	4M20D	1/21/2018	N	Head trauma	
Asian Elephant	327	0.1	6Y+	1/22/2018	Y	Geriatric decline, severe chronic osteoarthritis	
Peacock Clownfish	18106	0.5	Adult	1/28/2018	N	Presumptive water quality issue	
Red-legged Serpema	17654	0.1	24Y7M11D	2/3/2018	N	Metastatic carcinoma	
Goldenail Moray Eel	18075	1.0	13Y1M17D	2/3/2018	N	Possibly related to branchitis	
Four eyed fish	18107	1.0	Adult	2/3/2018	N	Cardiac disease	
Four eyed fish	18107	0.1	Adult	2/4/2018	N	Undetermined	
Red billed firefinch	17804	0.1	1Y2M9D	2/5/2018	N	Undetermined	
Red billed firefinch	17417	0.1	2Y10M28D	2/10/2018	N	Hepatic amyloidosis, possible fungal ventriculitis	
Piny Hawkfish	15709	0.0.1	Geriatric	2/12/2018	N	Ceolomic cavity sarcoma/neoplasia	
Sebas short tailed bat	14700	0.1	Geriatric	2/14/2018	N	Geriatric decline, kidney disease	
Pangasius Catfish	14593	0.1	Adult	2/24/2018	N	Septicemia	
Cut-throat finch	17581	0.1	2Y5M10D	2/27/2018	N	Enteritis, hepatitis, septicemia	No necropsy able to be performed
Northern Seahorse	18102	0.1	Adult	3/1/2018	N	Anaplastic sarcoma	
Arctic Fox	15524	0.1	10Y9M1D	3/2/2018	Y		
Discus	18096/18104	0.1	Adult	3/2/2018	N	Failure to thrive	
Naked Mole Rat	G18109	0.0.1	newborn	3/10/2018	N	Failure to thrive	
Naked Mole Rat	G18109	0.0.1	newborn	3/10/2018	N	Failure to thrive	
Alabara Tortoise	18112	0.0.1	In egg	3/10/2018	Y	Failure to hatch, manually hatched ; sepsis	
Annulated Boa	16440	1.0	18Y4M6D	3/13/2018	Y	Geriatric decline, chronic gastritis	
Sebas short tailed bat	14700	0.1	Geriatric	3/14/2018	Y	Geriatric decline	
Northern Seahorse	15944	1.0	Geriatric	3/14/2018	N	Undetermined/geriatric decline	
Mexican Giant Tree Frog	16647D	0.0.1	Adult	3/15/2018	N	Hepatic necrosis/undetermined	
Plecotomus	13660	0.0.1	Unk	3/16/2018	N	Undetermined	
Desert Millipede				3/17/2018	N	Undetermined	
Jamaican Fruit bat	14660	0.1	Geriatric	3/18/2018	N	Presumed geriatric decline	No necropsy performed due to PMA
Red billed firefinch	17869	0.1	1Y2M	3/19/2018	N	Undetermined	
Four eyed fish	18107	0.0.3	Adult	3/21/2018	N	Undetermined/hepatic lipidosis	
Four eyed fish	18107	0.0.1	Adult	3/22/2018	N	Undetermined/hepatic lipidosis	
Four eyed fish	18107	0.0.1	Adult	3/22/2018	N	Undetermined	
Boeseman's Rainbowfish	18065	0.0.1	Unk	3/23/2018	N	Undetermined	
Desert Millipede				3/24/2018	N	Undetermined	
Northern Seahorse	18102	0.1	Adult	3/25/2018	N	Undetermined	Unable to be necropsied/PMA
Four eyed fish	18107		Adult	3/27/2018	N	Undetermined/hepatic lipidosis	
Alabara Tortoise	18113	0.0.1	Juv	3/29/2018	Y	Multiple congenital malformations	
Desert Millipede				3/30/2018	N	Undetermined	
Tentacled Snake	17314D	0.1	Adult	4/5/2018	N	Ceolomitis/egg yolk ceolomitis	
Chameleon goby	15775	0.0.1	Unk	4/6/2018	N	Undetermined	

Species	Local ID	Sex	Age	Date of Death	Euthanized	Cause of death/reason for euthanasia	Other notes
Northern Seahorse	17845	0.1	Adult	4/6/2018	N	Sepsis, mycobacterial disease	
Alligator Snapping Turtle	9553	1.0	Unk, >70y	4/7/2018	N	Multifactorial, renal disease, hepatic lipidosis	
Striped hermit crab	16285		Unk	4/13/2018	N	Undetermined/PMA	
White Rhino	5590	1.0	37Y3D	4/16/2018	Y	Metastatic carcinoma	
Jamaican Fruit bat	14650		Geriatric	4/17/2018	N	Presumed geriatric decline	
Coustelets Chameleon	17676	0.1	2Y11M1D	4/17/2018	N	Metastatic lymphosarcoma	
Domestic Rat	17680	0.1	2Y1M12D	4/18/2018	Y	Mycoplasma pneumonia	
Tinfoil barb	13578	0.0.1	Adult	4/18/2018	N	Undetermined; unknown age and some signs of trauma	
Plesiosaurus	15894	0.0.1	Adult	4/19/2018	N	Undetermined	Unable to be necropsied
Northern Seahorse	18102	0.0.1	Adult	4/25/2018	N	Undetermined	Unable to be necropsied/PMA
Sebas short tailed bat	17506	0.1	Geriatric	4/26/2018	N	Presumed geriatric decline	
Parsons Finch	17600	0.0.1	3Y8M13D	4/26/2018	N	Head trauma, pneumonia	
Northern Seahorse	18102	0.0.1	Adult	4/26/2018	N	Undetermined	Unable to be necropsied/PMA
Northern Seahorse	15844	1.0	Geriatric	4/28/2018	Y	Gas bubble disease, geriatric decline, hepatic lipidosis	
Red Rumped Cacique	16852 or 16853	0.1		5/1/2018	N	Undetermined	No necropsy able to be performed
American Flamingo	13851	0.1	20Y10M13D	5/2/2018	Y	Degenerative joint disease/instability, lymphoma	
Green Jay	17084	1.0	5Y10M22D	5/7/2018	N	Aspergillosis	
Jamaican Boa	18162	stillborn	stillborn	5/8/2018	N	Undetermined	
Catfish	15772	0.0.1	Adult	5/8/2018	N	Undetermined	Unable to be necropsied/PMA
Spotted Turtle	17537	0.1	4Y11M14D	5/15/2018	N	Conspecific trauma/multiorgan inflammation	
Namaqua Dove	16749	1.0	8Y16D	5/16/2018	N	Undetermined	No necropsy able to be performed
Alabara Tortoise	18160	0.0.1	stillborn	5/16/2018	N	Fetal malformation	
Boeseman's Rainbowfish	18065	0.0.1	Adult	5/18/2018	N	Undetermined	Unable to be necropsied/PMA
Mexican Giant Tree Frog	16847R	0.0.1	Adult	5/19/2018	N	Undetermined/spinal trauma	
Northern Seahorse	15945	0.2	Adult	5/22/2018	N	Systemic mycobacteriosis	
Cornsnake	14592	1.0	18Y11D	5/26/2018	N	Neoplasia/hemorrhage	
White rumped seedeater	16687	0.0.1	6Y8M3D	5/30/2018	N	Pneumonia and possible vit E deficiency	
Crested Coia	16628	0.1	6Y2M2D	6/5/2018	N	Predation, ratsnake	
Northern Seahorse	18129B	1.0	Adult	6/7/2018	Y	Systemic mycobacteriosis	
Naked Mole Rat	18166	0.0.3	newborn	6/9/2018	N	failure to thrive/lack of maternal care	
Two toed sloth	8058	0.1	40Y30D	6/14/2018	N	Drowning, kidney disease	
Tropical	17301	0.1	6Y1M13D	6/14/2018	N	Predation, ratsnake	
Red billed firefinch	17841	1.0	1Y7M12D	6/17/2018	N	Hepatic and cardiac amyloidosis	
Northern Seahorse	15845	0.1	Geriatric	6/18/2018	N	Undetermined	Unable to be necropsied/PMA
Wormpoo fruit dove	18207	0.0.1	hatching	6/19/2018	N	Undetermined	No necropsy able to be performed
African Penguin	14365	0.1	29Y3M12D	6/23/2018	N	Undetermined, probable trauma	
Phantasmal Poison Dart Frog	17028	0.0.1	Adult	6/23/2018	N	Undetermined	Post mortem autolysis
Yellow Foot Tortoise	1283	0.1	46Y8M12D	6/25/2018	N	Renal disease	
Indian Silverbill	17136	0.0.1	4Y24D	6/26/2018	N	Undetermined	
Northern Seahorse	15845	0.1	Geriatric	7/2/2018	N	Undetermined	Unable to be necropsied
Namaqua Dove	17187	1.0	>4Y	7/5/2018	N	Neurologic abnormalities/white muscle disease	No necropsy able to be performed
Scarlet Ibis	11968	1.0	26Y11M19D	7/8/2018	Y		
Magpie Shrike	16629	0.1	7Y2M11D	7/9/2018	N	Conspecific trauma	
Agassiz's catfish	18105	0.0.1	Adult	7/11/2018	N	Undetermined	Unable to be necropsied/PMA
Northern Seahorse	15845	0.1	Geriatric	7/12/2018	N	Undetermined	Unable to be necropsied/PMA
Blue capped Cordon-bleu	18190	0.0.1	fledgling	7/13/2018	N	head trauma	
Magpie Shrike	18050	1.0	7Y2M17D	7/16/2018	N	Predation, ratsnake	
Netherland dwarf rabbit	15178	1.0	13Y2M3D	7/18/2018	Y	Geriatric decline, metastatic adrenal carcinoma	
Yellow Rumped Cacique	16845	1.0	6Y1M20D	7/20/2018	N	Presumed infection/possibly viral	
Shamang	16827	0.1	31Y9M19D	7/26/2018	Y	Bacterial pyelonephritis	
Northern Seahorse	16129B	1.0	Adult	7/26/2018	N	Bacterial sepsis	
Sebas short tailed bat	14700	0.1	Geriatric	8/4/2018	N	Geriatric decline	

Species	Local ID	Sex	Age	Date of Death	Euthanized	Cause of death/reason for euthanasia	Other notes
Four eyed fish	18107		Adult	8/5/2018	N	Undetermined	Unable to be necropsied/PMA
Grey Tree Frog	16281	0.0.1	Unk	8/8/2018	N	Undetermined	
Red Piranha	17140		Adult	8/10/2018	Y	Conspecific trauma	
Golfodulcean Poison Dart Frog	16319D	0.0.1	Unk	8/10/2018	N	Undetermined	Unable to necropsy
Banded Rock Rattlesnake	16346	1.0	20Y7M4D	8/15/2018	Y	Spinal discospondylitis/spondylitis	
Blessed Poison Dart Frog	18164	0.0.1	Unk	8/16/2018	N	Bacterial hepatitis	
Oklahoma Salamander	17741	0.1	Unk	8/17/2018	Y	Renal failure	
Sebas short tailed bat	14700	0.1	Geriatric	8/20/2018	N	Geriatric decline	
African Pygmy goose	17948	0.1	2Y5D	8/20/2018	N	Undetermined/GI hemorrhage	
Double striped thick knee	16615	0.1	6Y2M7D	8/25/2018	Y	Severe pulmonary hemorrhage; left leg fracture	
Firefinch	18225	0.0.1	<1M	9/3/2018	N	Conspecific trauma	
Firefinch	18226	0.0.1	<1m	9/3/2018	N	Conspecific trauma	
Sambava tomato frog	17905	0.0.1	7Y6M2SD	9/3/2018	N	Multiple, myositis, nephritis, hepatitis	
Butterfly splitfin	14086	0.1	Adult	9/6/2018	N	Reproductive tract infection, septicemia	
Golfodulcean Poison Dart Frog	17200	0.0.1	Unk	9/10/2018	N	Undetermined	
North American Porcupine	16330	0.1	11Y4M27D	9/11/2018	N	Cardiovascular disease, pheochromocytoma	
Sebas short tailed bat	14700	0.1	Geriatric	9/13/2018	N	Geriatric decline	
Undetermined finch nestling		0.0.1		9/14/2018	N	Undetermined	Unable to be necropsied
Undetermined finch nestling	15845	0.1	Geriatric	9/15/2018	N	Undetermined	Unable to be necropsied
Undetermined finch nestling		0.0.1		9/16/2018	N	Undetermined	
Undetermined finch nestling	15845	0.1	Geriatric	9/16/2018	N	Undetermined	
Sebas short tailed bat	14700	0.1	Geriatric	9/18/2018	N	presumed geriatric decline	Unable to be necropsied
Indigobird	17944		Adult	9/25/2018	N	Possible bacterial pneumonia	
Cut-throat finch	17680	1.0	Adult	9/25/2018	N	Undetermined	No necropsy able to be performed
Four eyed fish	18197	1.0	Unk	9/27/2018	N	Hypothermia	
Blue tongued skink	10576	0.1	28Y6M5D	10/6/2018	Y	Severe progressive osteoarthritis	
Northern Seahorse	16129B		Adult	10/8/2018	Y	Myobacterial pyelonephritis	
Vermillion grouper	16460		Adult	10/11/2018	N	Jumped out of tank	
Green Iguana	14417	0.1	22Y6M11D	10/12/2018	Y	Progressive osteoarthritis, cecidomitis	
Jamaican Fruit bat	14680	0.0.1	Geriatric	10/21/2018	N	presumed geriatric decline	
Mission Milky Tree Frog	16276	0.0.1	Unk	10/22/2018	N	Undetermined/bacterial dermatitis	
Firefinch	18237	0.1	Adult	10/23/2018	N	Traumatically conspecific	
Bearded Dragon	16072	0.1	10Y6M24D	10/28/2018	Y	Non-resectable liver/gall bladder abnormalities	
Firefinch	16721	1.0	>6y	10/30/2018	N	Kidney failure/amyloidosis	
Northern Seahorse	15845	0.1	Geriatric	10/30/2018	N	Undetermined, suspected mycobacteriosis	
Firefinch	17117	1.0	4Y	11/2/2018	Y	Amyloidosis, large leg hemangiomas	
Black Howler	11844	0.1	24Y1M5D	11/7/2018	Y	End stage renal failure	
Chuckwalla				11/8/2018	Y	Undetermined	
Jamaican Fruit bat	14660	0.1	Geriatric	11/9/2018	N	Geriatric decline	
Northern Seahorse	16129B	0.0.1	Adult	11/9/2018	N	Undetermined	
Tentacled Snake	17314R	0.0.1	Juv	11/10/2018	N	Undetermined	too autolyzed for postmortem exam
Black Footed Cat	16964	1.0	6Y10M20D	11/11/2018	Y	Renal failure	
Bleeding Heart Dove	17943	1.0	4Y6M26D	11/14/2018	N	Left foot progressive degenerative joint disease	
American Flamingo	13972	1.0	24Y4M12D	11/15/2018	Y	Bacterial dermatitis	
Mission Milky Tree Frog	16276	0.0.1	Unk	11/15/2018	N	Fractured right leg, conspecific trauma	
Springbok	17685	1.0	4Y10M15D	11/20/2018	Y	failure to thrive/lack of maternal care	
Naked Mole Rat	18268	0.0.1	newborn	11/21/2018	N	Trauma	
Naked Mole Rat	18268	0.0.1	newborn	11/22/2018	N	Renal failure	
Naked Mole Rat	18268	0.0.1	newborn	11/23/2018	N	failure to thrive/lack of maternal care	
Naked Mole Rat	18268	0.0.4	newborn	11/24/2018	N	failure to thrive/lack of maternal care	
Naked Mole Rat	18268	0.0.1	newborn	11/25/2018	N	failure to thrive/lack of maternal care	

Species	Local ID	Sex	Age	Date of Death	Euthanized	Cause of death/reason for euthanasia	Other notes
Henkels Leaf tailed gecko	18210	0.0.1	3M16D	11/27/2018	N	Undetermined/enteritis	
Boeseman's Rainbowfish	18065	0.0.1	Adult	11/28/2018	N	Undetermined	Unable to be necropsied/PMA
Parsons Finch		0.0.1	Chick	11/30/2018	N	Undetermined	No necropsy able to be performed
Red Tailed Catfish	16457	0.0.1	Adult	12/2/2018	N	Supersaturation event	
Tiger Shovelnose	14651	0.0.1	Adult	12/2/2018	N	Supersaturation event	
Pacu	14737	0.0.1	Adult	12/2/2018	N	Supersaturation event	
Midas Cichlid	14911	0.0.258	various	12/2/2018	N	Supersaturation event	
Blue Tilapia	18093	0.0.7	Adult	12/2/2018	N	Supersaturation event	
Firefinch	16716	1.0	>6yr	12/3/2018	N	Amyloidosis; gout	
Midas Cichlid	14911	0.0.27	various	12/3/2018	N	Supersaturation event	
Parsons Finch	18204	0.0.1	4M22D	12/4/2018	N	Undetermined	
Tentacled Snake	17314R	0.0.3	juv	12/4/2018	N	Failure to thrive	too autolyzed for postmortem exam
Firefinch	18234	0.1	5M14D	12/7/2018	N	Trauma	
Northern Seahorse	15845	0.1	Geriatric	12/7/2018	N	Systemic mycobacteriosis	
American Flamingo	15405	1.0	11Y6M9D	12/10/2018	Y	Systemic amyloidosis and gout	
Northern Tree Shrew	16772	1.0	6Y5M25D	12/12/2018	Y	Hepatic neoplasia	
Black & White Ruffed Lemur	11815	1.0	31Y1M11D	12/12/2018	N	Anesthetic death; geriatric/cardiovascular disease	
Northern Seahorse	15845	0.1	Geriatric	12/15/2018	Y	Weight loss	
Northern Seahorse	15945	0.1	Geriatric	12/15/2018	Y	Mycobacteriosis	
Northern Seahorse	16129B	0.0.1	Adult	12/16/2018	N	Undetermined	Unable to be necropsied/PMA
Namaqua Dove	16751	0.1	6Y4M23D	12/20/2018	N	Renal failure	
Henkels Leaf tailed gecko	17512	1.0	4Y5M13D	12/20/2018	N	Undetermined	
Tentacled Snake	17314R	0.0.1	juv	12/21/2018	N	Failure to thrive/secondary fungal dermatitis	
Tentacled Snake	17314R	0.0.1	juv	12/21/2018	N	Failure to thrive/secondary fungal dermatitis	Representative necropsy on other
Tentacled Snake	17314R	0.2	juv	12/21/2018	Y	Failure to thrive/secondary fungal dermatitis	Representative necropsy on other
Derbyan Parakeet	18165	0.0.1	6M26D	12/26/2018	N	Renal gout; head trauma	
Henkels Leaf tailed gecko	17421	1.0	5Y1M27D	12/26/2018	N	Hepatic lipidosis	
Henkels Leaf tailed gecko	17751	0.0.1	2Y6M1D	12/26/2018	N	Hepatic lipidosis	
Henkels Leaf tailed gecko	17924	0.0.1	1Y8M4D	12/26/2018	N	Undetermined/hepatic lipidosis	
Boeseman's Rainbowfish	18065	0.0.1	Adult	12/27/2018	N	Undetermined	Unable to be necropsied/PMA
Tentacled Snake	17314R	0.0.1	juv	12/28/2018	N	Failure to thrive/secondary fungal dermatitis	Representative necropsy on other
Banded Rock Rattlesnake	17267	0.1	5Y5M17D	12/30/2018	N	Undetermined	too autolyzed for postmortem exam
Grey capped Emerald Dove	18205	1.0	4M23D	12/31/2018	N	Fungal Inguinitis, secondary aspiration pneumonia	Unable to be necropsied/PMA
Northern Seahorse	15945	0.1	Geriatric	12/31/2018	N	Undetermined	
Jamaican Boa	17871	1.0	~20Y	1/1/2019	N	Bacterial sepsis	
Tentacled Snake	17314R	0.0.3	juv	1/2/2019	N	Failure to thrive	
Tentacled Snake	17314R	0.0.1	juv	1/2/2019	N	Failure to thrive	
Tentacled Snake	17314R	0.0.1	juv	1/2/2019	Y	Failure to thrive	
Blue capped cordon bleu	17966	0.1	1Y5M24D	1/3/2019	N	Head trauma	
Seba's Short Tailed Bat	14700	0.1	Geriatric	1/6/2019	N	Geriatric decline	
Tentacled Snake	17314R	0.0.1	juv	1/10/2019	N	Failure to thrive	
Oustalet's chameleon	18248	0.1	1Y6M23D	1/11/2019	N	Fungal sepsis	
Calfish	15772	0.0.1	Adult	1/12/2019	N	Branchitis	
Seba's Short Tailed Bat	14700	0.1	Geriatric	1/14/2019	N	Geriatric decline	
Red billed Firefinch	17817	0.1	2Y3M	1/17/2019	N	Amyloidosis	
Madagascar Buttonquail	17150	1.0	5Y2M30D	1/17/2019	N	Heart base sarcoma	
Boeseman's Rainbowfish	18065	0.0.1	Adult	1/19/2019	N	Mycobacterial nephritis	
Cut throat finch	16486	1.0	9Y6M19D	1/20/2019	N	Undetermined	unable to necropsy, post mortem changes
Northern Seahorse	16129B	0.0.1	Adult	1/21/2019	N	Undetermined	Too autolyzed for post mortem evaluation
Black throated finch	17501	0.0.1	5Y7M6D	1/26/2019	N	Undetermined	unable to necropsy, post mortem changes
Emperor Spotted Newt	16783	1.0	Geriatric	1/27/2019	N	Geriatric/renal disease	
Red billed Firefinch	18235	0.1	7M6D	1/29/2019	N	Trauma/window strike	

Species	Local ID	Sex	Age	Date of Death	Euthanized	Cause of death/reason for euthanasia	Other notes
Emperor Spotted Newt	16784	0.0.1	Geriatric	1/29/2019	N	Undetermined	Too autolyzed for histopathology
Northern Seahorse	16129B	1.0	Adult	1/30/2019	N	Undetermined	Too autolyzed for post mortem evaluation
Emperor spotted Newt	17604	0.0.1	Adult	2/1/2019	N	Undetermined/hepatic lipidosis	
Henkel's Leaf tailed gecko	18060	1.0	1Y1M25D	2/2/2019	N	Undetermined; hepatic inflammation	
Northern Seahorse	15945	0.1	Adult	2/2/2019	N	Mycobacteriosis	
Red Legged Seriema	3287	1.0	40Y	2/6/2019	Y	Geriatric decline; arthritis, cardiovascular disease	
Blue Spiny Lizard	16512	0.0.1	7Y5M21D	2/7/2019	Y	Heart/lung mineralization; possible nutritional imbalance	
Golden headed lion tamarin	14851	1.0	14Y3M4D	2/11/2019	Y	Renal disease	
Giant Madagascar Day Gecko	18246	0.1	7Y1M11D	2/12/2019	Y	Trauma	Too autolyzed for post mortem evaluation
Convict Cichlid	13234	0.0.1	Adult	2/16/2019	N	Undetermined	
North American Porcupine	18017	0.1	7Y6M26D	2/19/2019	N	Intestinal mass/intussusception	Too autolyzed for post mortem evaluation
Northern Seahorse	15945	0.1	Geriatric	2/19/2019	N	Undetermined	
Sunbittern	17251	1.0	13Y4M8D	2/22/2019	N	Trauma/window strike	
Golfodulcean poison dart frog	16319D	0.0.1	Adult	2/23/2019	N	Undetermined	
Cut throat finch	17715	0.1	2Y6M9D	2/25/2019	N	Undetermined	unable to necropsy, post mortem changes
Kalahdin sheep	15767	0.1	10Y1M2D	2/27/2019	Y	Geriatric decline; dental atrition	
Saba's Short Tailed Bat	14700	0.1	Geriatric	2/27/2019	N	Geriatric decline; endometriosis/pyometra	
Boeseman's Rainbowfish	18065	0.0.2	Adult	2/28/2019	Y	Ulcerative dermatitis	
Oklahoma Salamander	17741	0.1	Adult	3/1/2019	Y	Renal disease	
Giant Madagascar Day Gecko	18053	0.1	Adult	3/2/2019	N	Renal failure	
Phantasmal Poison Dart Frog	17072B	0.0.1	Adult	3/2/2019	N	Undetermined	
Plush crested Jay	14342	0.1	19Y10M1D	3/16/2019	Y	Geriatric decline; decreased mobility/arthritis	
Boeseman's Rainbowfish	18065	0.0.1	Adult	3/24/2019	N	Undetermined	Too autolyzed for post mortem evaluation
Pinktail chalcous	15368	0.0.1	Adult	3/26/2019	N	Undetermined	Too autolyzed for post mortem evaluation
Oustalet's chameleon	17677	0.1	3Y10M20D	4/5/2019	N	Chronic kidney disease	
Northern Seahorse	16129B	Adult	Adult	4/5/2019	Y	Mycobacteriosis	
Red billed firefinch	17624	1.0	3Y5M	4/10/2019	N	Undetermined	unable to necropsy, post mortem changes
Northern Seahorse	15945	0.1	Adult	4/12/2019	N	Undetermined	Too autolyzed for post mortem evaluation
Pyrra	16995	0.0.1	Adult	4/25/2019	Y	Parasitic bronchitis	
Slender Tailed Meerkat	16288	0.1	10Y7M29D	5/1/2019	Y	Intestinal adhesions/peritonitis	
Nomequa Dove	16750	0.1	8Y10M19D	5/5/2019	N	Kidney failure/disease	
Black throated finch	18289	0.0.1	3M2D	5/7/2019	N	Systemic gout	
Red billed Firefinch	17807	1.0	2Y7M26D	5/8/2019	N	Renal gout/hepatic amyloidosis	
Naked Mole Rat	G18311	0.0.1	neonate	5/11/2019	N	Pneumonia	
Green crested basilisk	16392	1.0	Adult	5/11/2019	N	Bacterial colitis, presumptive septicemia	
Four banded sandgrouse	16825	0.1	6Y9M18D	5/13/2019	N	Presumptive head trauma	
Panther chameleon	17952	0.1	1Y10M19D	5/16/2019	N	Bacterial septicemia, renal gout	
Boeseman's Rainbowfish	18065	0.0.1	Adult	5/17/2019	N	Undetermined	Too autolyzed for post mortem evaluation
Spotted Turtle	14486	0.1	25Y3D	5/18/2019	N	Kidney disease	
Blue Spiny Lizard	16509	0.1	7Y9M5D	5/21/2019	N	Vascular thrombosis; cardioresp crystals	
Pyrra	16995	0.0.1	Adult	5/23/2019	N	Cardiovascular disease	
Catfish	16772	0.0.1	Adult	5/24/2019	Y	pending	
Blue crowned pigeon	12296	1.0	25Y24D	5/25/2019	Y	Severe arthritis	
Chuckwalla	16541	0.1	7Y8M20D	6/2/2019	N	Dystocia	
Naked Mole Rat	17480	0.1	6Y2D	6/9/2019	N	Conspecific trauma	

Seattle Aquarium
1483 Alaskan Way
Seattle, WA 98101
May 20th, 2019



SEATTLE AQUARIUM

1483 Alaskan Way, Pier 59
Seattle, Washington 98101-2015

(206) 386-4300
SeattleAquarium.org

Dear Mr. Kick,

Thank you for your inquiry. We fully support discussions on animal health and welfare; those discussions are an inherent part of our mission and day-to-day work.

We frequently provide results from necropsies and ancillary diagnostics to researchers to evaluate and publish. Current examples include a review of North American river otters (*Lontra canadensis*) lead by the University of Illinois and a review of stranded sea turtles lead by the National Oceanic and Atmospheric Administration (NOAA).

We also share data with the Association of Zoos and Aquariums (AZA) taxon-advisory groups and species-survival plans so that the information is available to a wide audience. A large part of our regular accreditation process by the AZA also includes animal health and welfare. These accreditation standards are available on-line.

This collaborative data sharing provides everyone with valuable evidence-based information, while avoiding the potential pitfalls of taking records out of context and misinterpreting medical language. And it encourages valuable follow-up investigations as indicated by the data.

We have only had one mammal mortality in 2018 and 2019. This was a 20-year-old river otter with age-related changes. The paper on river otters being published by the University of Illinois will provide a more complete picture of how river otters are doing under human care.

The Washington State Public Records Act (Chapter 42.56 RCW) is important legislation to increase transparency in state or local government agencies. We are a private, not-for-profit conservation organization and are not run by any state or local agency. We are happy to include our most recent USDA report that shows no concerns. We would also appreciate the opportunity to show you the work that we do at the Seattle Aquarium. Please let us know if you plan to visit Seattle and would like a tour of the facility.

Yours sincerely,

Brad Rutherford
Chief Operating Officer



Recycled content

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United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES

2016082569258375 Insp_id

Inspection Report

Seattle Aquarium Society
1483 Alaskan Way, Pier #59
Seattle, WA 98101

Customer ID: 324097
Certificate: 91-C-0124
Site: 001
Seattle Aquarium Society

Type: ROUTINE INSPECTION
Date: 29-AUG-2018

No non-compliant items identified during this inspection.

This inspection and exit briefing were conducted with the facility representatives.

Prepared By:

DIANE FORBES

Digitally signed by DIANE FORBES
DN: c=US, o=U.S. Government, ou=Department of Agriculture,
cn=DIANE FORBES,
0.9.2342.19200300.100.1.1=12001000107285
Date: 2018.08.30 10:00:40 -07'00'

FORBES DIANE, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 5053

Received By:

TRACI BELTING VIA EMAIL

Title: CURATOR OF MAMMALS & BIRDS

Date:
30-AUG-2018

Date:
30-AUG-2018



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
324097	91-C-0124	001	Seattle Aquarium Society	29-AUG-18

Count	Scientific Name	Common Name
000002	<i>Callorhinus ursinus</i>	NORTHERN FUR SEAL
000004	<i>Enhydra lutris</i>	SEA OTTER
000001	<i>Lontra canadensis</i>	NORTH AMERICAN RIVER OTTER
000003	<i>Phoca vitulina</i>	HARBOR SEAL
000010	Total	



UNIVERSITY OF
SOUTH CAROLINA

Office of the General Counsel

January 22, 2020

Mr. Russ Kirk
New England Anti-Vivisection Society
333 Washington Street, Ste. 850
Boston, MA 02108

Re: Freedom of Information Act Request

Dear Mr. Kirk:

This is in response to the South Carolina Freedom of Information Act request that you recently directed to the University of South Carolina. Enclosed herewith are copies of the documents that you requested.

A total of 52 copies are enclosed, and the University charges 5 cents per copy. Therefore, please mail a check payable to "University of South Carolina" in the amount of \$2.60 to my attention at the address below.

Please contact me if you have any questions in connection with your request.

Sincerely,

George W. Lampl, III
Associate General Counsel



UNIVERSITY OF
SOUTH CAROLINA

Office of Research

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

December 5, 2019

School of Medicine Building 3 - Conference Room 225

Institutional Animal Care
and Use Committee

The December 5, 2019 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:01pm.

Committee Members Present:

Dr. Shannon Davis	IACUC Chair
Committee Member IA	
Committee Member 45	
Committee Member 52	
Committee Member 71	
Committee Member 123	
Committee Member 125	
Committee Member 128	

*late arrival **early departure ***non-voting

I. APPROVAL OF MINUTES

The committee voted 8-0 to approve the November minutes.

II. CHAIRMAN'S ANNOUNCEMENTS

A. There were no announcements.

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

A. There were no announcements.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

A. The January 2020 deadline is December 11, 2019.

V. OLD BUSINESS

2382-101223-92117	Approved by Designated Review
2419-101345-072318	Approved by Designated Review
2367-101253-071817	Approved by Designated Review
2364-101193-060217	In Review.
2414-101320-052218	In Review.
2349-101211-041917	Approved by Designated Review

2342-101188-032217	Approval pending IBC.
101445	There was no response from the PI; administratively withdrawn.
2385-101287-100417	Approved by Designated Review
2397-101285-110617	Approved by Designated Review
2335-101179-022817	In Review.
2450-101426-042219	Approved by Designated Review
101468	Approved by Designated Review
2374-101258-080217	Approved by Designated Review
2389-101244-101317	In Review.
101461	In Review.
101466	In Review.

VI. NEW BUSINESS

A. Annual Reviews

1. Renewals

2404-101311-012318	Approved.
2438-101388-012219	Approved.

2. Terminations

None.

B. New Administrative Action

1. Pending Amendments

2376-101215-081617	<i>(personnel)</i>
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2. Approved Amendments

2471-101457-102119	<i>(fund, personnel)</i>
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3. Other

None.

C. New Veterinary Verifications/Consults

2412-101315-032818	Approved by Designated Review
2434-101342-110518	In Review.
2363-101196-053117	Approved by Designated Review
2459-101447-070819	In Review.

D. New Designated Member Determinations & Reviews

1. Pending

None.

2. Assigned

None.

E. Full Committee Reviews

- 2437-101355-121318 The committee voted 8-0 to require modifications to secure approval.
The modifications requested are attached.
- 2466-101450-082819 The committee voted 8-0 to require modifications to secure approval.
The modifications requested are attached.
- 101471 The committee voted 8-0 to require modifications to secure approval.
The modifications requested are attached.

F. Compliance Activities

1. Follow-up. PI# 21, reference 101315. The PI submitted the requested modifications via amendment and they were approved.
2. New.

VII. OTHER BUSINESS

- A. VA inspection dates. The IACUC Administrator is working toward getting VA inspections on the same schedule as UofSC inspections, which will ease current time, staff, reporting issues related to institutional collaboration.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for January 9, 2020 at 3:00 pm in SOM Building 3, Conference Room 225. The meeting deadline is December 11, 2019.

IX. ADJOURN

The meeting was adjourned at 3:35pm.

Protocol Review Comments Summary Report
Reference Number 101355

Section: Administrative

Question: Protocol Associates

Comments: Please include information on who will perform the perfusions as well as his/her training and experience.

Section: Study Objectives

Question: Lay Summary

Comments: Several parts of lay summary are redundant. For example, "The current treatment options for VM are very limited. There is an urgent need to develop more effective therapeutic strategies for VM treatment" repeats the previous sentences.

Section: Animals and Procedures

Question: Procedure Description

Comments: Please change "mice" to "rats" near the bottom of this section.

Question: Procedure Description

Comments:

1. What substance will be used to disinfect the skin for microdialysis?
2. Please provide a description of the perfusion procedure.

Question: Strain/Stock/Breed

Comments: The layout for some of the projects makes it difficult to follow how many animals will be used for that project, as well as add-on experiments 7 & 8. For example, Project 6 has a total of 1400 animals written in red font, then additional mice needed for projects 7 & 8 are described, and a new total of 2150 is given. Consider revising the writing style to state that "750 additional mice will be required for 7 & 8, bringing the total to 2150." The current writing style makes it appear that 1400 + 2150 animals are needed.

Question: Category E

Comments: Animals undergoing ketamine-induced seizures should be placed in category E.

Question: Phenotype Management

Comments:

1. How will heartbeat and temperature be monitored?
2. What are the cutoff values/endpoints used to remove animals from the study?

Question: Breeding Numbers

Comments: It is indicated that n=84 SMA-CreERT2/Rosa26stop-floxedEYFP/bdnf2lox offspring will be weaned but 498 will be used. It is also indicated that n=84 SM22a-CreERT2(ki)/Rosa26EYFP /bdnf2lox+/- /Pvl-YFP offspring will be weaned but 264 will be used. Please correct these numbers as the number of offspring weaned cannot be less than the number of offspring used.

Question: Description of Experimental Design

Comments:

1. Animals experiencing seizures should be placed in Category E.
2. For the new experiment added in Project 7, is seizure testing at 12-15 months necessary if mice develop most of the pathology they are prone to at 6-8 months (this is noted in Project 6 description)? For some of these mice the phenotype is unknown at present; the PI so may want to consider fewer mice at an earlier timepoint, depending on phenotype/pathology observed.
3. If mice are monitored for a total of 60 min after kainic acid, why are they not sacrificed within a few hours (current protocol states 2 days)? Please clarify.
4. Stage 6 on the Racine scale is tonic-clonic seizure/convulsion/death - will animals be monitored for any time after the initial 60 mins to check on their welfare? Please clarify.

Question: Chemical Euthanasia Agents

Comments: TO AV: It seems that Pentobarbital (euthasol) should be given at a standard dose to all mice, not within a range of 30-90 mg/kg? Is this correct?

Comments: Please modify the description from "will be inserted perpendicularly through the apex of left ventricle of the heart" to "needle will be inserted into the left ventricle via the apex of the heart parallel to the septum."

Question: Experimental Agents/Diets

Comments: The ink is not administered until after death; please select "no."

Protocol Review Comments Summary Report
Reference Number 101450

Section: Amendment Information

Question: Type of Amendment

Comments: Please also select "Change of Animal Number or Type".

Section: Administrative

Question: Protocol Associates

Comments:

1. Please indicate who will be handling the Peromyscus.
2. While very similar to Mus, Peromyscus are different; please indicate how you will be trained in handling these animals.

Section: Animals and Procedures

Question: Species Selection

Comments: Peromyscus are not Laboratory Mice. Please select them under "Species Selection" and complete the sections that appear. Delete all references to Peromyscus under the Laboratory Mice section.

Question: Strains Not Listed

Comments: Peromyscus are not Laboratory Mice. Please select them under "Species Selection" and complete the sections that appear. Delete all references to Peromyscus under the Laboratory Mice section.

Section: Alternatives and Duplication

Question: Consideration of Alternatives

Comments: Please update the search to include Peromyscus.

Protocol Review Comments Summary Report
Reference Number 101471

Section: Administrative

Comments: If funded, this AUP will fall under DOD guidelines for the care and use of laboratory animals.

Question: Protocol Associates

Comments: The PI is currently not up to date with his AALAS surgical modules. He was assigned the modules:

Aseptic Technique for Rodent Survival Surgery, Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress

Section: Animals and Procedures

Question: Animal Number Justification

Comments:

1. How was the group size of 8 determined? Did you do a power analysis? Please clarify.
2. The last two sentences regarding GWI and perfusion do not seem pertinent to this section; they may be deleted.

Question: Description of Experimental Design

Comments:

1. Please provide a schematic diagram of the timeline of the experiments to better understand the treatments and their rationale.
2. The endpoints are not well defined. How will the impact of the exosome treatments be assessed? What markers will be measured? Will behavioral measurements be made? What tissues will be collected? The endpoints need to be better described.
3. Are there any deleterious effects of the treatments on the mice? If so, how will they be handled?
4. Briefly describe "tube restraint." Why is it a better model than other types of restraint?
5. Please provide a scientific justification for the dosing regimen. If this is intended to model GWI, it is unclear why PB is only administered "tri-weekly," as soldiers were taking PB daily.
6. Please provide a scientific justification for the 10 min duration for restraint stress as this is rather short for a chronic restraint paradigm.

Question: Euthanasia Methods

Comments:

1. Does cardiac puncture occur before or after euthanasia? Please clarify.
2. Anesthetic overdose, as described here, would be the primary method of euthanasia.

Question: Procedure Description

Comments: Please clarify, in the first sentence, that the mark on the gavage tube is used as a guide to determine when to stop advancing the tube, and incorporate this into the procedure description.

Question: Experimental Agent Table

Comments: Please indicate the source for permethrin.

Question: Location

Comments: These are not immunizations. Please select "Intraperitoneal injection."

Question: Procedure Description

Comments: Please indicate that injection volumes will be less than 1 ml.

Question: Procedure Description

Comments: Cardiac puncture prior to euthanasia is not tissue collection after euthanasia. If cardiac puncture occurs before euthanasia, please clarify this; if it occurs after euthanasia, delete this section and add the appropriate procedure instead (Intravascular blood withdrawal).

Question: Procedure Description

Comments:

1. Please correct the grammar of "After general anesthesia and mice in sleep..."
2. The description should include the % of isoflurane in chamber and to indicate how one will determine whether the mouse is fully anesthetized.

Question: Prolonged Restraint Justification

Comments:

1. Please justify the use of such a brief, 10-min daily stressor in keeping with the objective of deployment stress--members of the military were not exposed to only 10 mins of stress per day, experimental justification should be provided.
2. If the restraint is intended to be stressful, it goes against the use of this as a stressful experience to conduct "familiarization" and "positive reinforcement," both of which REDUCE the stress of the restraint tube. For the sake of study design the acclimatization components should be removed from the procedure.

Question: Handling of Exposed Items

Comments: Please select "yes" and complete the section.



UNIVERSITY OF
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Office of Research

Institutional Animal Care
and Use Committee

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

November 8, 2019

School of Medicine Building 3 - Conference Room 225

The November 8, 2019 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:03pm.

Committee Members Present:

Dr. Shannon Davis	IACUC Chair
Dr. Shayne Barlow	Attending Veterinarian
Committee Member IA	
Committee Member 01	
Committee Member 45	
Committee Member 52	
Committee Member 71	
Committee Member 77	
Committee Member 91	
Committee Member 121	
Committee Member 128	

*late arrival **early departure ***non-voting

I. APPROVAL OF MINUTES

The committee voted 9-0 to approve the October minutes.

II. CHAIRMAN'S ANNOUNCEMENTS

A. Microsoft Teams. After a brief discussion, it was agreed that committee members would be added to the current Microsoft Teams account.

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

- A. USC Aiken site visit.** The AV discussed the November 5th visit to the Aiken campus with the IACUC Administrator. Aiken was advised regarding requirements of the PHS Assurance process. Their program would consist of approximately five protocols.
- B. PAM changes.** DLAR is developing a QA/QC/lab liaison position, which will require revision of the PAM policy. It should be available for review and discussion at the December meeting.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

- A. **Assent documents.** Assent documents for the IACUC review process were circulated for signatures.
- B. **Semi-annual Program Review and Inspection Report.** The report was circulated for signatures.
- C. **Overdue AALAS member training.**

V. OLD BUSINESS

2435-101360-120418	Approved by Designated Review.
2401-101292-112817	Approved by Designated Review.
2398-101289-111717	Approved by Designated Review.
2399-101260-111717	Approved by Designated Review.
2399-101260-111717	Approved by Designated Review.
2393-101263-102717	Approved by Designated Review.
2385-101287-100417	Approved by Designated Review.
2382-101223-092117	In Review.
2426-101349-090518	Approved by Designated Review.
2461-101448-081419	Approved by Designated Review.
2419-101345-072318	In Review.
2367-101253-071817	In Review.
2459-101447-070819	Approved by Designated Review.
2418-101326-062818	Approved by Designated Review.
2458-101418-061219	Approved by Designated Review.
2364-101193-060217	In Review.
2414-101320-052218	In Review.
2452-101425-050119	Approved by Designated Review.
2450-101426-042219	Approved by Designated Review.
2349-101211-041917	In Review.
2443-101407-040319	Approved by Designated Review.
2342-101188-032217	Approval pending IBC.
101310	Approved by Designated Review.
101445	In Review.
101457	Approved by Designated Review.
101462	Approved by Designated Review.
101463	Approved by Designated Review.
101464	Approved by Designated Review.

VI. NEW BUSINESS

A. Annual Reviews

1. Renewals

2436-101380-121118	Approved.
2385-101287-100417	In Review.

2437-101355-121318 Approved.
2402-101304-112917 Approved.
2397-101285-110617 In Review.

2. Terminations

None.

B. New Administrative Action

1. Pending Amendments

2445-101410-041019 In Review.
2335-101179-022817 Incomplete; returned without review.

2. Approved Amendments

2469-101310-093019
2372-101257-073117

2457-101434-051519
2455-101389-050819
2452-101425-050119

2346-101204-041317
2345-101192-032817
2341-101198-032217
2340-101195-031317

3. Other

None.

C. New Veterinary Verifications/Consults

2418-101326-062818 Approved.
2450-101426-042219 In Review.
101310 Approved.

D. New Designated Member Determinations & Reviews

1. Pending

None.

2. Assigned

101468 In Review.
2374-101258-080217 In Review.

E. Full Committee Reviews

2389-101244-101317 The committee voted 8-0-1 to require modifications to
secure approval. The requested modifications are attached.

101467 The committee voted 9-0 to require modifications to secure approval. The requested modifications are attached.

101466 The committee voted 9-0 to require modifications to secure approval. The requested modifications are attached.

F. Compliance Activities

1. Follow-up. None.
2. New.

PI# 21, reference 101315. DLAR staff reported concerns about research personnel exceeding endpoints and providing veterinary treatment without consultation. The committee voted 9-0 to require modifications for a complete description of the model. The PI will be contacted by phone and by email as soon as possible.

VII. OTHER BUSINESS

A. None.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for December 5, 2019 at 3:00 pm in SOM Building 3, Conference Room 225. The meeting deadline is November 20, 2019.

IX. ADJOURN

The meeting was adjourned at 3:52pm.

Protocol Review Comments Summary Report
Reference Number 101244

Section: Administrative

Comments:

Question: Protocol Associates

Comments: Please indicate which associates will perform intracranial injections, and provide their training/experience with the procedure.

Section: Animals and Procedures

Question: Description of Experimental Design

Comments: What are the units of 10^{12} ? Please clarify.

Question: Experimental Agent Table

Comments: Please move the agents for intracranial injection to the appropriate section. This section is for intraperitoneal injections.

Question: Postoperative Monitoring and Care

Comments: This section is incomplete. Please revise to include the surgical staples and when they will be removed.

Protocol Review Comments Summary
Reference Number 101461

Section: Administrative

Question: Protocol Associates

Comments: In the Comments section, please provide the PI's training and years of experience with research animals and the procedures.

Section: Project Information

Question: Funding Source

Comments: No proposals or awards are found in USCERA. Please only add funded grants that have assigned account numbers.

Question: Identify 'other' funding source.

Comments: Please select "Department/University-wide programs" from the drop-down menu for Funding Source above and delete the information in this section.

Section: Animals and Procedures

Question: Procedure Description

Comments: Please change 'deplete muscle glycogen' to 'deplete liver glycogen.'

Question: Location

Comments: This cannot be performed in an animal room. Please select a procedure room.

Question: Procedure Description

Comments: Please include a full description of the procedure here, including that death will be assured (and how) prior to exsanguination or tissue collection.

Question: Surgical Procedure

Comments:

1. Please indicate the anatomical location for the skin incision.
2. Please provide the distance between the two drill holes, and whether they are bilateral or unilateral.
3. Please provide the expected, elapsed time from injection to needle removal.
4. Please indicate if the drill holes will be filled with bone wax or another substance before closing the incision.

Question: Postoperative or Preemptive Analgesics

Comments: DLAR cannot provide controlled substances. PIs must obtain appropriate licensure and secure the agents independently.

Question: Handling of Exposed Items

Comments: Please select "yes" and complete the section.

Protocol Review Comments Summary
Reference Number 101466

Section: Administrative

Question: Protocol Associates

Comments:

1. For Protocol Associates it states they were trained in August 2019 but that they have no experience in vertebrate animal work. Please clarify what they received training for.
2. If a Protocol Associate will not work with live animals, please remove her from the protocol.
3. For the PI, please address his potential duties in Responsibilities and his training in Comments.
4. If the PI may perform surgeries, please add him to Surgical Personnel.

Section: Animals and Procedures

Question: Animal Number Justification

Comments:

1. Please provide animal numbers in #8. Animals bred and transferred from the institution must be counted.
2. The numbers don't match the spreadsheet. Please clarify.
3. In addition to the spreadsheet, a summary table would be helpful.

Question: Surgical Preparation

Comments: Proper aseptic technique involves using three alternating cycles of betadine followed by 70% isopropanol. Please adjust this section accordingly.

Section: Alternatives and Duplication

Question: Consideration of Alternatives

Comments: This section states, "This search encompassed the period of 1965 to October 2018." Please update the year.



UNIVERSITY OF
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Office of Research

Institutional Animal Care
and Use Committee

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

October 3, 2019

School of Medicine Building 3 - Conference Room 225

The October 3, 2019 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:07pm.

Committee Members Present:

Dr. Shannon Davis	IACUC Chair
Dr. Shayne Barlow	Attending Veterinarian
Committee Member IA	
Committee Member 45	
Committee Member 121	
Committee Member 125	
Committee Member 128**	

*late arrival **early departure ***non-voting

I. APPROVAL OF MINUTES

The committee voted 8-0 to approve the September minutes.

II. CHAIRMAN'S ANNOUNCEMENTS

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

A. Security: Carolina Card conversion project. The project is complete and most users have facility access.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

A. Assent documents. Assent documents for the IACUC review process were circulated for signatures.

B. Semi-annual Program Review and Inspection Report. The report was circulated for signatures.

C. VA parking changes. Changes to parking at the VA were updated and discussed. VA and SOM stickers should plan on parking across the street. USC stickers can park in the lot between buildings 10 and 28 or other visitor parking, based on availability.

V. OLD BUSINESS

2401-101292-112817 Approved by Designated Review.

2399-101260-111717 In Review.

2391-101279-102417	Approved by Designated Review.
2385-101287-100417	In Review.
2386-101286-100417	Approved by Designated Review.
2382-101223-092117	In Review.
2368-101255-072417	Approved by Designated Review.
2419-101345-072318	In Review.
2459-101447-070819	In Review.
2418-101326-062818	In Review.
2416-101092-061518	In Review.
2458-101418-061219	In Review.
2364-101193-060217	In Review.
2414-101320-052218	In Review.
2450-101426-042219	Approved by Designated Review.
2349-101211-041917	In Review.
2342-101188-032217	In Review.
101310	In Review.
101430	Approved by Designated Review.
101445	In Review.
101457	In Review.
101462	In Review.

VI. NEW BUSINESS

A. Annual Reviews

1. Renewals

2388-101202-100417	Approved.
2393-101263-102717	In Review.
2398-101289-111717	In Review.
2399-101260-111717	In Review.
2400-101293-112017	Approved.
2401-101292-112817	In Review.
2434-101342-110518	Approved.
2435-101360-120418	In Review.

2. Terminations

None.

B. New Administrative Action

1. Pending Amendments

2450-101426-042219	In Review.
2367-101253-071817	In Review.
2452-101425-050119	In Review.

2. Approved Amendments

2325-101159-121416
2369-101242-072617

2376-101215-081617
2383-101273-092117
2450-101426-042219
2451-101423-042519
2462-101413-081619
2466-101450-082819

3. Other
None.

C. New Veterinary Verifications/Consults
None.

D. New Designated Member Determinations & Reviews

1. Pending

2393-101263-102717 In Review.

2. Assigned

2426-101349-090518 In Review.
2461-101448-081419 In Review.
2443-101407-040319 In Review.
101463 In Review.

E. Full Committee Reviews

101464 The committee voted 8-0 to required modifications to
secure approval. The modifications requested are attached.

F. Compliance Activities

1. Follow-up. None.
2. New. None.

VII. OTHER BUSINESS

- A. The Chair initiated a discussion regarding placing a secure-access file drop for storing IACUC documents, reports, and materials that committee members need on a long-term or recurrent basis. He will look into options and report back to the committee next month.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for November 7, 2019 at 3:00 pm in SOM Building 3, Conference Room 225. The meeting deadline is October 30, 2019.

IX. ADJOURN

The meeting was adjourned at 3:29pm.

Protocol Review Comments Summary
Reference Number 101464

Section: Administrative

Question: Protocol Associates

Comments: In the 'Comments' section for all associates, only include training and experience pertinent to their duties listed on this proposal. Oral gavage, retro-orbital bleeding, and breeding are not part of this study.

Section: Animals and Procedures

Question: Authorized Amounts

Comments: Because animals are likely to experience side-effects such as weight loss, diarrhea, and respiratory distress associated with the chemotherapeutic drugs, associated pain or distress will not be momentary or transient. These animals should be in pain category D (if analgesia will be provided) or E (if analgesia will not be provided).

Question: Category E

Comments: Because animals are likely to experience side-effects such as weight loss, diarrhea, and respiratory distress associated with the chemotherapeutic drugs, and pain or distress will not be alleviated with analgesics, these animals should be category E.

Question: Animal Number Justification

Comments: 60 animals are requested, but experiments with 40 mice are justified. Please outline plans for the remaining 20 animals.

Question: Euthanasia Methods

Comments: In the comments section, please state how the animal will be anesthetized.

Question: Procedure Description

Comments: Please limit injection volumes to 1 ml.

Question: Duration and Frequency of the Procedure

Comments: How many weeks will each animal receive cyclosporine injections?

Question: Location

Comments: Animals cannot be euthanized and tissues collected in an animal housing room. Please select another location.

Question: Procedure Description

Comments:

1. Two different injection volumes are described. Please revise for consistency.
2. Please limit injection volume to 1 ml.
3. Use of a 30-gauge needle may reduce injection-associated pain and could be considered.

Section: Pharmaceutical Grade Compounds

Question: Non-Pharmaceutical Grade Compounds

Comments: DMSO is also purchased from Sigma and not pharmaceutical grade. Please add it to the table.



UNIVERSITY OF
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INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Institutional Animal Care
and Use Committee

September 5, 2019

School of Medicine Building 3 - Conference Room 225

The September 5, 2019 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Shannon Davis, Chair, at 3:07pm.

Committee Members Present:

Dr. Shannon Davis	IACUC Chair
Dr. Shayne Barlow	Attending Veterinarian
Committee Member 52	
Committee Member 86	
Committee Member 71	
Committee Member IA	
Committee Member 01	
Committee Member 121	
Committee Member 77	

*late arrival **early departure ***non-voting

I. APPROVAL OF MINUTES

The committee voted 9-0 to approve the August minutes.

II. CHAIRMAN'S ANNOUNCEMENTS

Dr. Davis introduced a new faculty member of the committee (#121).

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

- A. The Discovery and GSRC systems are back on, and temperatures and humidity control have equilibrated to normal.
- B. The installation of the Carolina Card upgrade continues. Some users have reported problems with access; these issues have been resolved on a case-by-case basis.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

- A. Semi-annual program review and inspections have been completed. The report will be circulated for review and signatures at the October meeting.
- B. A new meeting schedule is included in the hard-copy materials. It should be posted on the website.
- C. The recommendations of the 21st Century Cures Act to reduced administrative burden in animal research were discussed.
- D. The VA is preparing for new construction that will eliminate a significant amount of parking. This will particularly affect off-campus members of the committee. Sections of the Cedar Terrace Shopping Center have been leased for overflow parking, which entails crossing all of Garner's Ferry Road. The email and maps will be provided to the committee.

V. OLD BUSINESS

101354	Approved by Designated Review.
101413	Approved by Designated Review.
101430	In Review.
101440	Approved by Designated Review.
101443	Approved by Designated Review.
101445	In Review.
101448	Approved by Designated Review.
101449	Approved by Designated Review.
101450	Approved by Designated Review.
101451	Approved by Designated Review.
101452	Approved by Designated Review.
2341-101198-032217	Approved by Designated Review.
2342-101188-032217	In Review.
2363-101196-053117	Approved by Designated Review.
2364-101193-060217	In Review.
2368-101255-072417	Approved by Designated Review.
2377-101266-082317	Approved by Designated Review.
2379-101225-083117	Approved by Designated Review.
2382-101223-092117	In Review.
2385-101287-100417	In Review.
2399-101260-111717	In Review.
2401-101292-112817	In Review.
2413-101332-052218	Approved by Designated Review.
2414-101320-052218	In Review.
2416-101092-061518	In Review. The Chair will contact the PI regarding this submission.
2418-101326-062818	In Review.
2419-101345-072318	In Review.
2424-101227-082218	Approved by Designated Review.

VI. NEW BUSINESS

A. Annual Reviews

1. Renewals

2383-101273-092117	Approved by Designated Review.
2431-101368-100218	In Review.
2428-101352-091718	Approved by Designated Review.
2426-101349-090518	Approved by Designated Review.
2429-101353-091718	Approved by Designated Review.
2391-101279-102417	In Review.
2386-101286-100417	In Review.
2433-101359-101018	Approved by Designated Review.
2430-101373-091818	Approved by Designated Review.
2396-101278-103017	Approved by Designated Review.

2432-101337-100818

Approved by Designated Review.

2. Terminations

None.

B. New Administrative Action

1. Pending Amendments

2368-101255-072417

2459-101447-070819

2. Approved Amendments

2344-101185-032817

2412-101315-032818

2461-101448-081419

2422-101348-081318

2393-101263-102717

2377-101266-082317

2374-101258-080217

2372-101257-073117

2371-101254-072617

2370-101265-072617

2365-101250-062917

2363-101196-053117

2357-101217-051817

2355-101205-051517

2346-101204-041317

2346-101204-041317

2345-101192-032817

2345-101192-032817

2340-101195-031317

2340-101195-031317

2337-101183-030317

2323-101158-111816

3. Other

2387-101272-100417

Termination requested by the PI.

2440-101392-030519

Termination requested by the PI.

2448-101424-042219

Termination requested by the PI.

C. New Veterinary Verifications/Consults

2461-101448-081419

Termination requested by the PI.

2450-101426-042219

In Review.

2329-101161-121916

In Review.

D. New Designated Member Determinations & Reviews

1. Pending

101462

101463

2. Assigned

2436-101380-121118 Approved by Designated Review.

2349-101211-041917 Approved by Designated Review.

2458-101418-061219 In Review.

E. Full Committee Reviews

101310 The committee voted 8-0-1 to required modifications to secure approval. The modifications requested are attached.

101457 The committee voted 9-0 to required modifications to secure approval. The modifications requested are attached.

F. Compliance Activities

1. Follow-up. None.

2. New. None.

VII. OTHER BUSINESS

1. CVs/biosketches. The Administrator requested updated CVs or biosketches from the committee members.
2. PI #16 lab manager vacancy. The AV and the Chair met with the department head and PI regarding the quality of applicants. The decision was made to have research staff from the department chair's lab oversee activities through the end of the year, and reassess the position in January 2020. The IACUC voted 9-0 to accept the action.
3. USC Aiken subgrant protocol and IIA. A protocol was submitted to the IACUC from USC Aiken, related to a pending inter-institutional agreement for receipt of federal funding (USC Aiken has its own IACUC, but not its own PHS Assurance). The IACUC found that the protocol was not compliant with standards and policies, and voted 9-0 to decline acceptance of the protocol. It will recommend to the Institutional Official that USC Aiken either obtain its own Assurance, or that it choose to have its animal work and protocol review come under the purview of the USC IACUC as utilized by the rest of the USC system.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for October 3, 2019 at 3:00 pm in SOM Building 3, Conference Room 225. The meeting deadline is September 25, 2019.

IX. ADJOURN

The meeting was adjourned at 4:09pm.

Protocol Review Comments Summary
Reference Number 101310

Section: Administrative

Question: Protocol Associates

Comments:

1. Please correct the comments section as 2 protocol associates are not listed on this proposal.
2. In the protocol associate comment section, please provide more information regarding training and experience with the animals and procedures.
3. As written, 6 protocol associates will be the only associates approved to perform blood collection a blood withdrawal. Please add blood collection to the responsibilities section for all associates that will perform the procedure(s).
4. Please remove references to breeding; breeding is not included in this proposal.

Section: Animals and Procedures

Question: Animal Number Justification

Comments:

1. This section exceeds the 2000-character limit for the section. Please provide a brief list of the experiments and include the full narrative as an attachment.
2. Please define PDX.

Question: Description of Experimental Design

Comments: Please clarify why estradiol will be administered orally, as it is not as effective as using a slow-release pellet administered via trochar.

Question: Procedure Description

Comments:

1. Injection volumes should be less than 1 ml. If a larger volume is required, please provide a scientific justification.
2. IP injection can be done without anesthesia - is it necessary to anesthetize the mice?

Question: Duration and Frequency of the Procedure

Comments: Please alternate injection sites to avoid irritation, especially for mice receiving 18 injections.

Question: Procedure Description

Comments: Tail vein bleeding is discussed in the experimental design (Part 2) but is not described here. Please clarify.

Question: Duration and Frequency of the Procedure

Comments: How many times will blood be drawn from a single animal using this method?

Question: Surgical Personnel Experience

Comments: In the second column, please provide the years of experience with the species for surgical associates.

Question: Surgical Preparation

Comments:

1. This section should include "animals will be examined to make sure they are not ill; any signs of illness will result in removal from the study".
2. Please revise the sentence, "Turn on the heating pad and set the water temperature to 38°C" to "Animal body temperature will be maintained at 37 degrees C by a heating pad". Please indicate how real body temperature will be monitored, which should be automatically controlled by the heating pad.

Question: Surgical Procedure

Comments:

1. Please clarify how bleeding will be controlled.
2. Please clarify the "clinical signs" that will be monitored post-surgery and include them in the Post Monitoring and Care section.
3. Please clarify if the exact area, either left or right side behind the neck, where the mini pump will be inserted.
4. Please indicate the size (cm) of the small incision for each surgery.

Question: Instrument Sterilization

Comments: Please modify the last sentence to "Surgical bench area will be disinfected by wiping with a DLAR-approved disinfectant."

Question: Postoperative or Preemptive Analgesics

Comments: Will all animals get both agents? Please clarify this in the postoperative care section.

Question: Surgical Preparation

Comments: Hair must be removed from the surgical site.

Question: Surgical Procedure

Comments: How will waste anesthetic gases be scavenged when a bell jar/cone apparatus is used?

Section: Alternatives and Duplication

Question: Rationale for Animal Use

Comments: Please provide a rationale for each strain of mouse used.

Protocol Review Comments Summary
Reference Number 101457

Section: Study Objectives

Comments: Throughout the protocol, please replace "rats" with "mice." Rats are not part of the study as described.

Section: Animals and Procedures

Question: Category E

Comments: All animals receiving electric shock are category E. Please select "yes" and fill out the section.

Question: Animal Number Justification

Comments:

1. Will breeding be performed on this protocol? Please clarify.
2. All offspring need to be accounted for here, in Authorized Amounts, and in the Breeding number sections.
3. It is assumed the KMO het and KO mice described here will have to be genotyped following breeding. Please describe the genotype procedure to be employed. Please note that genotyped animals undergoing no further procedures fall under USDA pain category C.

Question: Source of Animals

Comments: Breeding is described in the experimental design section. Please select it as a source of animals and complete the section.

Question: Institution Identity

Comments: Which strain(s) will come from this source? Please clarify.

Question: Description of Experimental Design

Comments:

1. In-house breeding (as part of this protocol) has not been selected as a source of animals, though breeding is described here.
2. At least one instance of 'rat chow' (Methods of administration section) is used; please change it to 'rodent chow'.
3. Euthanasia using sharp scissors is listed in the euthanasia section. Please include the use of this methodology as being specifically for neonates.
4. In the Behavioral studies paragraph, please change "rats" to "mice."

Question: Procedure Description

Comments:

1. It states here that "....will be placed into individual rat cages". This proposal only lists mice. Please clarify.
2. In the first sentence, rat chow is mentioned; please change it to rodent chow.
3. How often will the custom diet be replaced?
4. How often will the ceramic dishes be sterilized, and how?

Question: Procedure Description

Comments: Please replace "rats" with "mice."

Question: Procedure Description

Comments: In this context, the Fruit Loops would be considered a special diet or enrichment.

Please select "Administration of Special Diet" as a procedure and fill out the section.
Please provide more information regarding the source of Fruit Loops, storage, etc.

Question: Animal Housing

Comments: Is this correct? It appears that animals on the medicated diet will be individually housed. Please clarify.



UNIVERSITY OF
SOUTH CAROLINA

Office of Research

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

August 1, 2019

School of Medicine Building 3 - Conference Room 225

Institutional Animal Care
and Use Committee

The August 1, 2019 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Ken Walsh, Chair, at 3:05pm.

Committee Members Present:

Dr. Ken Walsh	IACUC Chair
Dr. Shayne Barlow	Attending Veterinarian
Committee Member 45	
Committee Member 52	
Committee Member 86	
Committee Member 98	
Committee Member 125	

Consultants and Guests

IACUC Administrator

*late arrival **early departure ***non-voting

The committee deferred the agenda to the next convened meeting.

I. APPROVAL OF MINUTES

The committee voted 7-0 to approve the minutes.

II. CHAIRMAN'S ANNOUNCEMENTS

Dr. Walsh announced that he will step down as chair with the September meeting, and that Dr. Shannon Davis will be the new Chair.

III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS

- A. The steam outage at Discovery continues and cages are being sanitized chemically instead of with heat, as required per the Guide.
- B. The GSRC will experience a steam outage next week for sump pump repairs.

IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS

- A. Semi-annual inspections are due this month. An availability poll will be sent out, followed by calendar items when dates and times are chosen.

V. OLD BUSINESS

2325-101159-121416	Approved by Designated Review.
2401-101292-112817	In Review.
2323-101158-111816	Approved by Designated Review.
2399-101260-111717	In Review.

2395-101283-103017	Approved by Designated Review.
2393-101263-102717	Approved by Designated Review.
2389-101244-101317	Approved by Designated Review.
2433-101359-101018	Approved by Designated Review.
2385-101287-100417	Approved by Designated Review.
2383-101273-092117	Approved by Designated Review.
2426-101349-090518	Approved by Designated Review.
2376-101215-081617	Approved by Designated Review.
2421-101335-081318	Approved by Designated Review.
2419-101345-072318	Approved by Designated Review.
2416-101092-061518	Approved by Designated Review.
2364-101193-060217	Approved by Designated Review.
2363-101196-053117	In Review.
2413-101332-052218	In Review.
2453-101406-050119	In Review.
2352-101175-050117	Approved by Designated Review.
2446-101412-041019	Approved by Designated Review.
2343-101200-032217	Approved by Designated Review.
2342-101188-032217	Approved by Designated Review.
101413	In Review.
101430	In Review.
101440	In Review.
101447	In Review.
	Approved by Designated Review.

VI. NEW BUSINESS

A. Annual Reviews

1. Renewals

2395-101283-103017	Approved.
2390-101282-101317	Approved.
2389-101244-101317	Approved.
2384-101261-092817	Approved.
2382-101223-092117	In Review.
2381-101271-091317	Approved.
2380-101270-091217	Approved.
2379-101225-083117	In Review.
2425-101350-082718	Approved.
2424-101227-082218	In Review.
2422-101348-081318	Approved.
2373-101246-080217	Approved.

2. Terminations

2378-101275-083017	Termination requested by the PI.
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B. New Administrative Action

1. Pending Amendments

2418-101326-062818

2. Approved Amendments

2340-101195-031317

2341-101198-032217

2345-101192-032817

2346-101204-041317

2349-101211-041917

2457-101434-051519

2355-101205-051517

2357-101217-051817

2360-101224-052517

2363-101196-053117

2368-101255-072417

2370-101265-072617

2371-101254-072617

2372-101257-073117

2377-101266-082317

2407-101317-022118

2436-101380-121118

2444-101422-040519

2452-101425-050119

2459-101447-070819

3. Other

None.

C. New Veterinary Verifications/Consults

2335-101179-022817 Approved.

2352-101175-050117 Approved.

2377-101266-082317 Approved.

2412-101315-032818 Approved.

2425-101350-082718 Approved.

2450-101426-042219 Approved.

D. New Designated Member Determinations & Reviews

1. Pending

101450 In Review.

101452 In Review.

2. Assigned

2382-101223-092117 In Review.

2368-101255-072417	In Review.
2363-101196-053117	In Review.
2414-101320-052218	In Review.
2341-101198-032217	In Review.
101443	In Review.
101448	In Review.

E. Full Committee Reviews

101354	The committee voted 7-0 to require modifications to secure approval. The modifications requested are attached.
101445	The committee voted 7-0 to require modifications to secure approval. The modifications requested are attached.
101449	The committee voted 7-0 to require modifications to secure approval. The modifications requested are attached.
101451	The committee voted 7-0 to require modifications to secure approval. The modifications requested are attached.

F. Compliance Activities

1. Follow-up
2. New

A. PAM Surgical Observation. 2363-101196-053117 (skin graft).

VII. OTHER BUSINESS

1. PI#16 lab manager vacancy. The position was posted today.

VIII. NEXT MEETING

The next IACUC meeting is scheduled for September 5, 2019 at 3:00 pm in SOM Building 3, Conference Room 225. The meeting deadline is August 28, 2019.

IX. ADJOURN

The meeting was adjourned at 3:52pm.

Protocol Review Comments
Reference Number 101354

Section: Administrative

Question: Protocol Associates

Comments:

1. Please remove all references to breeding/mouse colonies as this proposal does not include breeding.
2. For the senior associates, please update their years of experience with the animals, procedures, and/or the PI's lab.
3. In the comments section for [Protocol Associate], should the second usage of LATA actually be AALAS? Please clarify.

Section: Animals and Procedures

Question: Strains Not Listed

Comments: Only parental strains need be listed above. This section can be deleted and the crosses can be described in the breeding section if animals are being bred.

Question: Authorized Amounts

Comments: These numbers cannot be corrected because the adjustment number interferes with the Authorized Amount fields. Please refer to other sections for the animal numbers. Authorized Amounts will be corrected on this AUP post approval.

Question: Category E Justification

Comments: Please expand on this justification. For example, how much pain or distress are animals expected to experience after surgery?

Question: Surgical Personnel Experience

Comments: Please review and revise:

1. In the second column, please provide the associates training/experience with the species listed in this section.
2. In the third column, please provide the associates training/experience with the surgical procedures listed in this section.

Question: Surgical Preparation

Comments: Please indicate how animal body temperature will be maintained and, if so, how it will be accomplished.

Question: Authorized Amounts

Comments: TO REVIEWERS: These numbers cannot be corrected because the adjustment number interferes with the Authorized Amounts field. Please refer to other sections for the animal numbers. Authorized Amounts will be corrected on this AUP post approval.

Question: Surgical Personnel Experience

Comments: Please review and revise:

1. In the second column, please provide the associates training/experience with the species listed in this section.
2. In the third column, please provide the associates training/experience with the surgical procedures listed in this section.

Review Comments Summary
Reference Number 101445

Section: Administrative

Question: Protocol Associates

Comments: Please indicate which associates will be responsible for the retro-orbital blood withdrawals, intravenous injections, and oral gavage.

Section: Animals and Procedures

Question: Strains Not Listed

Comments:

1. Please select the mice from the list above and delete them here.
2. Please provide the nomenclature and vendor information for the BDNF overexpressed mice so they can be added to the database selection as well.

Question: Authorized Amounts

Comments: Restraint as a model of stress should be category E.

Question: Category E

Comments: Select "Yes" and complete the section.

Question: Animal Number Justification

Comments: Some clarification on purpose/phenotype of additional mice used (e.g. HMGB1 KO or BDNF overexpressed mouse) would be beneficial understanding why they are needed for the experiments described. This information should also be in the Rationale for Animal Use section.

Question: Description of Experimental Design

Comments:

1. From which mice will the exosomes be isolated? Is it the 'GWI mouse model and chemical exposure' group? If so, please describe how exosomes will be isolated prior to injection in other animals.
2. A retro orbital blood withdrawal is the only live collection described; will the exosomes be isolated from this procedure before mice euthanized?
3. How many exosomes will be administered, and at what concentration?
4. How does the investigator ensure that purified exosomes are obtained, versus, for example, aggregated proteins that may illicit inflammatory responses?
5. Please indicate that a tube restraint model will be used.
6. Please indicate the expected resultant effects of some of the drug-induced disease models, particularly the GWI model that will be monitored for up to 20 weeks.
7. Describe the expected phenotype. How will successful development of the phenotype be ascertained?
8. Please define experimental endpoint criteria & veterinary care for all groups.

Question: Euthanasia Methods

Comments: Include all euthanasia methods described in the protocol.

Question: Duration and Frequency of the Procedure

Comments: Please include the duration of the procedure per animal - how long does the procedure take to complete?

Question: Duration and Frequency of the Procedure

Comments: Please include the duration of the procedure per animal - how long does the procedure take to complete?

Question: Procedure Description

Comments: Are these diets irradiated? If not, strong justification for their use is required.

Question: Procedure Description

Comments: If the injection will be conducted multiple times, will the injection site can be alternated? Please clarify.

Question: Duration and Frequency of the Procedure

Comments: Please include the duration of the procedure per animal - how long does the procedure take to complete?

Question: Location

Comments: Animals cannot be euthanized in the animal room. Please select an appropriate procedure room.

Question: Procedure Description

Comments: Please explain the anesthesia method and how waste gases will be scavenged.

Question: Duration and Frequency of the Procedure

Comments: There is no terminal surgery described in this AUP. Please clarify.

Question: Procedure Description

Comments: Please explain how the animal will be anesthetized and how waste gases will be scavenged.

Question: Duration and Frequency of the Procedure

Comments: Please include the duration of the procedure per animal - how long does the procedure take to complete?

Question: Food and/or Water Restriction Description

Comments: Please remove the phrase "be starved" and replace it with something appropriate, i.e., "have food withheld".

Review Comments Summary
Reference Number 101449

Section: Administrative

Question: Protocol Associates

Comments:

1. Please remove all instances of breeding as it is not included in this proposal.
2. Please replace all instances of AALAC with AALAS.
3. Please replace one instance of LATA with AALAS. [Protocol Associate]

Section: Animals and Procedures

Question: Authorized Amounts

Comments: Please reconcile the authorized amounts and pain categories with the animal numbers justification summary below.

Question: Category E Justification

Comments: Experiment 5 uses animals 28 days after injury. Please modify the last sentence.

Question: Animal Number Justification

Comments:

1. Please reconcile the animal numbers and pain categories (please list categories in your summary) with the animal numbers in Authorized Amounts.
2. Shouldn't animals in experiments 4 and 5, where a unilateral sciatic nerve crush is performed, also be in category E?

Question: Description of Experimental Design

Comments: In experiment 2, please clarify that pregnant rats will be euthanized before removal of E18 embryos.

Question: Surgical Personnel Experience

Comments:

1. Please remove all references to mice as this proposal only includes rats.
2. If the PI will be performing surgery, please include it in his 'Responsibilities' in the Protocol Associates section.

Question: Surgical Procedure

Comments: Please indicate how animal body temperature will be maintained during surgery.

Protocol Review Comments Summary
Reference Number 101451

Section: Administrative

Comments:

Question: Protocol Associates

Comments: Per the instructions, under "Comments", please summarize the experience/training of the individual as it relates to his/her duties on this proposal.

Section: Project Information

Question: Funding Source

Comments: Please identify the source of the account #A0001.

Question: Grant Number

Comments: Provide the associated account number (F1000x) in the Accounts section.

Section: Animals and Procedures

Question: Authorized Amounts

Comments: Mice that will not have induced colitis, such as those used only for breeding, should not be included in category E. For this protocol, breeding animals should be category B (breeding only) or category C (animals being genotyped).

Question: Animal Number Justification

Comments: Attachments should enhance, not replace, the requested information. Breeding colony numbers should be included in this justification.

Question: Description of Experimental Design

Comments:

1. As per the instructions, briefly explain the experimental design and provide a complete description of all experimental procedures that will be performed on the animals. This description should allow the IACUC to fully understand the experimental course of an animal or group of animals from its entry into the experiment to the endpoint of the study.
2. Additional humane endpoints should include hunched posture, failure to groom, inability to access food or water.

Question: Duration and Frequency of the Procedure

Comments: For the DSS-I3C or -DIM models, what determines the number of days ("up to 14") animals are injected?

Question: Procedure Description

Comments:

1. Is 3.5 cm too far into the rectum? Please describe the use of flexible tube/catheter, and provide assurance that puncture of the colon will not occur.
2. Justify why there is a need to wait for 25% weight loss before animals are euthanized. Weight loss is typically capped at 15%.

Question: Location
Comments: This should be an SoM animal room.

Question: Procedure Description
Comments: Please justify why there is a need to wait for 25% body weight loss before intervention. Weight loss is usually capped between 15.

Section: Pharmaceutical Grade Compounds

Question: Non-Pharmaceutical Grade Compounds
Comments: Some justifications are incomplete. It appears that none of these are available in a pharmaceutical grade, and a justification should be provided for each agent.



UNIVERSITY OF
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INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

June 27, 2019

1801 Grille – 700 Lincoln Street, Ste. 200

Institutional Animal Care
and Use Committee

The June 20, 2019 meeting of the University of South Carolina Institutional Animal Care and Use Committee (IACUC) was called to order by Ken Walsh, Chair, at 12:05pm.

Committee Members Present:

Dr. Ken Walsh	IACUC Chair
Dr. Shayne Barlow	Attending Veterinarian
Committee Member 01	
Committee Member	
Committee Member 52	
Committee Member 77	
Committee Member 86	
Committee Member 91	
Committee Member 98	

Consultants and Guests

IACUC Administrator

*late arrival **early departure ***non-voting

The committee deferred the agenda to the next convened meeting.

- I. APPROVAL OF MINUTES**
- II. CHAIRMAN'S ANNOUNCEMENTS**
- III. ATTENDING VETERINARIAN'S ANNOUNCEMENTS**
- IV. IACUC ADMINISTRATOR'S ANNOUNCEMENTS**
- V. OLD BUSINESS**
- VI. NEW BUSINESS**
 - A. Annual Reviews**
 - 2. Renewals
 - 3. Terminations
 - B. New Administrative Action**
 - 1. Pending Amendments
 - 2. Approved Amendments
 - 3. Other

C. New Veterinary Verifications/Consults

D. New Designated Member Determinations & Reviews

1. Pending
2. Assigned

E. Full Committee Reviews

F. Compliance Activities

VII. OTHER BUSINESS

VIII. NEXT MEETING

The next IACUC meeting is scheduled for August 1, 2019 at 3:00 pm in SOM Building 3, Conference Room 225. The meeting deadline is July 24, 2019.

IX. ADJOURN

U.S. Department of Labor

Occupational Safety and Health Administration
3300 Vickery Road
North Syracuse, New York 13212



Russ Kick
New England Anti-Vivisection Society
333 Washington Street, Suite 850
Boston, MA 02108

Re: SIMS #885322

Dear Mr. Kick:

This decision is in response to your Freedom of Information Act (FOIA) request dated November 14, 2019 and received in our office on November 20, 2019 requesting records concerning Marshall Farms Group, Ltd (I#1169727). We located the records you seek and conducted a review of the material you requested. After reviewing this information, we have made the following release determination.

Under FOIA, "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt" 5 U.S.C. § 552(b). Where we have withheld pages entirely, it is because those pages contain no reasonably segregable information that may be released without creating the harm the indicated exemptions were designed to prevent.

We have determined the following documents may be released with redaction:

1. Case File Diary Sheets, with personal identifying information redacted pursuant to Exemption 7(C)
2. Inspection Report, with number of employees redacted pursuant to Exemption 4; and personal identifying information redacted pursuant to Exemption 7(C)
3. Safety Narrative, with personal identifying information redacted pursuant to Exemption 7(C)
4. Photos, with personal identifying information redacted pursuant to Exemption 7(C)

Exemption 4 protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4). This exemption is intended to protect two categories of information in agency records: (1) trade secrets; and (2) certain confidential or privileged commercial information. We are withholding certain privileged or confidential information pursuant to Exemption 4. When applying this part of exemption 4, the terms "commercial or financial" should not be narrowly construed to include proprietary information only. Rather, they should be given their ordinary meaning.

Exemption 7(C) permits an agency to withhold information contained in files compiled for law enforcement purposes if production "could reasonably be expected to constitute an unwarranted

10/1/19

invasion of personal privacy.” 5 U.S.C. § 552(b)(7)(C). Thus, the purpose of Exemption 7(C) is to protect the privacy of any person mentioned in law enforcement records. In determining whether a protected privacy interest exists, we must evaluate not only the nature of the personal information found in the records, but also whether release of that information to the general public could affect that individual adversely. Thus, we must consider whether release of even seemingly innocuous personal information could lead to the harassment or annoyance of an individual through unsolicited inquiries. We find that release of personal identifying information withheld here reasonably could be expected to have a negative impact on an individual’s privacy.

The fees for this particular request totaled less than \$25.00; consequently, all fees have been waived.

You have the right to appeal this decision with the Solicitor of Labor within 90 days from the date of this letter. The appeal must state, in writing, the grounds for the appeal, including any supporting statements or arguments. The appeal should also include a copy of your initial request and a copy of this letter.

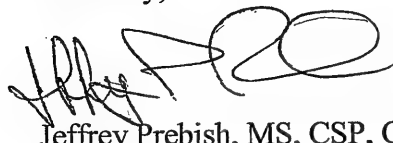
If you appeal, you may mail your appeal to: Solicitor of Labor, U.S. Department of Labor, Room N-2420, 200 Constitution Avenue, N.W., Washington, D.C. 20210 or fax your appeal to (202) 693-5538. Alternatively, you may email your appeal to foiaappeal@dol.gov; appeals submitted to any other email address will not be accepted. The envelope (if mailed), subject line (if emailed), or fax cover sheet (if faxed), and the letter indicating the grounds for appeal, should be clearly marked: “Freedom of Information Act Appeal.”

In addition to filing an appeal, you may contact the Department’s FOIA Public Liaison, Thomas G. Hicks, Sr. at (202) 693-5427 or hicks.thomas@dol.gov for assistance in resolving disputes.

You also may contact the Office of Government Information Services (OGIS) for assistance. OGIS offers mediation services to resolve disputes between FOIA requesters and federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. You may mail OGIS at the Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road – OGIS, College Park, MD 20740-6001. Alternatively, you may email or contact OGIS through its website at: ogis@nara.gov; Web: <https://ogis.archives.gov>. Finally, you can call or fax OGIS at: telephone: (202) 741-5770; fax: (202) 741-5769; toll-free: 1-877-684-6448.

It is also important to note that the services offered by OGIS, is not an alternative to filing an administrative FOIA appeal.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeffrey Prebish', is written over a horizontal line.

Jeffrey Prebish, MS, CSP, CIH
Area Director

1-2

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4

U.S. DOL - OSHA
CASE FILE DIARY SHEET

Follow-up Inspection # _____

(b) (7)(C)

Inspection # 1169727

Complaint # _____

Establishment Marshall Farms LTD

Site Address 5800 Lake Bluff Rd

City N Rose

State NY

Zip Code 14516

(b) (7)(C)

Er's Fax # _____

NACIS Code 112990

Er's Cell Phone # _____

Union ☒

Non Union ☐

SIC _____

U.S. DOL-OSHA

[illegible]

Company Name Marshall Farms LTD

Complaint # _____ Inspection # 116 9237

Date To Review Commission _____ Follow-Up # _____

U.S. Department of Labor - Occupational Safety and Health Administration

Inspection Report

Tue Oct 18, 2016 11:37:22 AM

RID	CSHO ID	Supervisor ID	Inspection Number	Optional Report Number	Case Closed Date
0215800	(b) (7)(C)		1169727		12-AUG-2016

Establishment Name	Marshall Farms Group, Ltd		Doing Business As (DBA)		
Establishment Owner Name	Private Sector	Type of Business	Corporation	Primary NAICS	112990
Site Address	5800 Lake Bluff Rd NORTH ROSE, NY, 14516	Site Phone	(b) (7)(C)	Extn	Site FAX
Business Address	5800 Lake Bluff Rd NORTH ROSE, NY, 14516	Business Phone			Business FAX
Mailing Address	5800 Lake Bluff Rd NORTH ROSE, NY, 14516	E-mail			Mobile Phone
Site Activity	dog production	NAICS Inspected	112990	Days on Site	1
Federal EIN		DUNS		Temporary or Fixed Site?	Fixed Site
State Estab Id		DUNS plus4		CAGE Code	
Construction Type					

Entry	12-AUG-2016		First Closing Conference	12-AUG-2016	
Opening Conference	12-AUG-2016		Second Closing Conference		
Walkaround	12-AUG-2016		Exit	12-AUG-2016	

Inspection Initiating Type	Program Planned		Secondary Type		
Other Initiating Type			Inspection Category	Safety	
Scope of Inspection	Comprehensive		Reason No Inspection		
Sampling Performed?	N	SVEP	N	Expln. for No Insp.	
Federal Strategic Initiatives	TRENCHING				
National Emphasis	TRENCH				
Local Emphasis					
Primary Emphasis	TRENCH				

Employed in Establishment	(b) (4)	Walkaround?	Y	Advance Notice?	N
Covered By Inspection		Interviewed?	Y	Flag for Follow-up	N
Controlled By Employer		Union?	N	Reason for Follow-up	
Is this Company a current federal contractor?	Y	Attempt made to capture Exec Order Info?	Y		

Parent Company Legal Name			Parent Comp Trade Name/DBA		
Parent Company Address		Phone Number		Extn	
TIN / EIN			DUNS		
CAGE Code			DUNS plus4		

Related Activity			
Activity Number	Activity Type	Satisfied	Establishment Name

Related Inspections		
Inspection Number	Establishment Name	Related Inspection Type
1169538	Montemarano Bros. Inc	MULTI-EMPLOYER

Additional Codes			
Type	ID	Value	Description

Employer Representatives Contacted					
Name	(b) (7)(C)	Job Title	(b) (7)(C)	Occupation	Animal production
Address		Interviewed?		Y	
Home		Work		Mobile	Fax
Email		Participation		Walk Around, Credentials, Closing Conference, Opening Conference	

Employees Contacted					
Name	(b) (7)(C)	Job Title	(b) (7)(C)	Occupation	
Address		Interviewed?		Y	
Home		Work	(b) (7)(C)	Mobile	Fax
Email		Participation		Walk Around, Credentials, Closing Conference, Opening Conference	

Penalty Adjustment Factors					
Size Reduction	10%	Good Faith Reduction	0%	History Reduction	0%
Size Justification	System, set it to 10% Number of Employees was changed	Good Faith Justification		History Justification	

CSHO Signature	(b) (7)(C)	
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SAFETY NARRATIVE

Inspection Number	1169727
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COVERAGE INFORMATION

The employer participates in Interstate Commerce through the breeding and sale of animals used for testing.

NATURE AND SCOPE

Check Applicable Boxes and Explain Findings:

☒ LEP
Trenching and Excavation.

NATURE AND SCOPE – UNUSUAL CIRCUMSTANCES (Mark X and explain all the apply:)

☒ None

OPENING CONFERENCE NOTES:

An inspection was started at this establishment on 8/12/16 based on a phone call to the SyrAO referencing an excavation that was not properly protected. Upon arrival, credentials were presented and an Opening Conference was held (b) (7)(C) Farms and (b) (7)(C) Co Inc. The reason and scope was explained to all in attendance at this time.

A visit to the excavation was conducted and pictures, measurements and sketches were taken. Interviews were conducted with all involved.

Montemarano Brothers were contracted by Marshall Farms to install storm water piping that had a diameter of 15 inches. This required a trench of up to 7.5 feet deep. In an interview with (b) (7)(C) he claimed to be the Competent Person for this job. (b) (7)(C) classified as Type (B) through ribbon testing and other soil classification methods and that it had a high cohesive strength and that he had properly protected his workers through benching. Pictures and sketches of the benching are contained in casefile. Interviews of (b) (7)(C) confirmed knowledge of standard and that (b) (7)(C) had indeed properly protected the workers. (b) (7)(C) admitted to being in the excavation and stated that he had no issues with protection and agreed with the use of benching.

RECORDKEEPING PROGRAMS

Does the employer have a record keeping program relating to any occupational health issues (monitoring, medical, training, respirator fit tests, ventilation measurements, etc.)?

☐ Yes ☒ No

Are any programs required by OSHA health standards?

☐ Yes ☒ No

COMPLIANCE PROGRAMS

The inspection of the worksite revealed that the excavation was in compliance with all standards.

PERSONAL HYGIENE FACILITIES AND PRACTICES

(showers, lockers, change rooms, etc.)

Are any required by OSHA health standards?

☐ Yes ☒ No

What Standards:

HAZARD COMMUNICATION PROGRAM

Written Program (complete)

☐ Yes ☒ No

MSDS's (all)

☐ Yes ☒ No

Labeling (adequate)

☐ Yes ☒ No

Training (complete)

☐ Yes ☒ No

Copy of MSDS's/Program attached

☐ Yes ☒ No

ACCESS TO EXPOSURE & MEDICAL RECORDS

N/A

FIRE PROTECTION AND EVACUATION PROCEDURES

N/A

SYSTEMS SAFETY AND EMERGENCY RESPONSE

911 to be called.

RESPIRATOR PROGRAM

N/A

LOCKOUT TAGOUT / ELECTRICAL SAFE WORKPRACTICES

N/A

FIRST AID

Equipment available onsite.

ELECTRICAL SAFE WORKPRACTICES

N/A

EXPOSURE CONTROL PLAN

N/A

LABORATORY STANDARD

N/A

ERGONOMIC PROBLEMS

☐ Yes ☒ No

EVALUATION OF EMPLOYER'S OVERALL SAFETY AND HEALTH PROGRAM

Construction Industry:

☒ Yes ☐ No Accident Prevention Program

☒ Yes ☐ No Written

☒ Yes ☐ No Copy Attached

Evaluation of Safety and Health Program

(0=Nonexistent 1=Inadequate 2=Average 3=Above average)

☒ Written S&H Program2

☒ Communication to Employees2

☒ Enforcement2

☒ Safety Training Program2

☒ Health Training Program2

☒ Accident Investigation Performed2

☒ Preventive Action Taken3

CLOSING CONFERENCE NOTES:

Were any unusual circumstances encountered such as, but not limited to, abatement problems, expected contest and/or negative employer attitude? If yes, explain below:

☐ Yes ☐ No

19. Closing Conference Checklist ("x" as appropriate)

- ☒ No Violations Observed
- ☐ Gave Copy Employer Rights
- ☐ Reviewed Hazards and Standards
- ☐ Discuss Employer Rights/Obligations
- ☐ Encouraged Informal Conference
- ☐ Offered Abatement Assistance
- ☐ Discussed Consultation Programs
- ☐ Employer/Employee Questionnaires

Closing Conference held with Employee Representative

☐ Jointly ☐ Separately

TO THE HONORABLE MEMBERS OF THE HOUSE OF REPRESENTATIVES

AND SENATORS OF THE SENATE

OF THE STATE OF NEW YORK

IN SENATE,

JANUARY 1, 1900.

REPORT

OF THE

COMMISSIONERS OF THE LAND OFFICE

IN RESPONSE TO A RESOLUTION

PASSED BY THE SENATE, APRIL 1, 1899.

ALBANY: J. B. LIPPINCOTT & COMPANY, PRINTERS.

1900.

NEW YORK: J. B. LIPPINCOTT & COMPANY, PRINTERS.

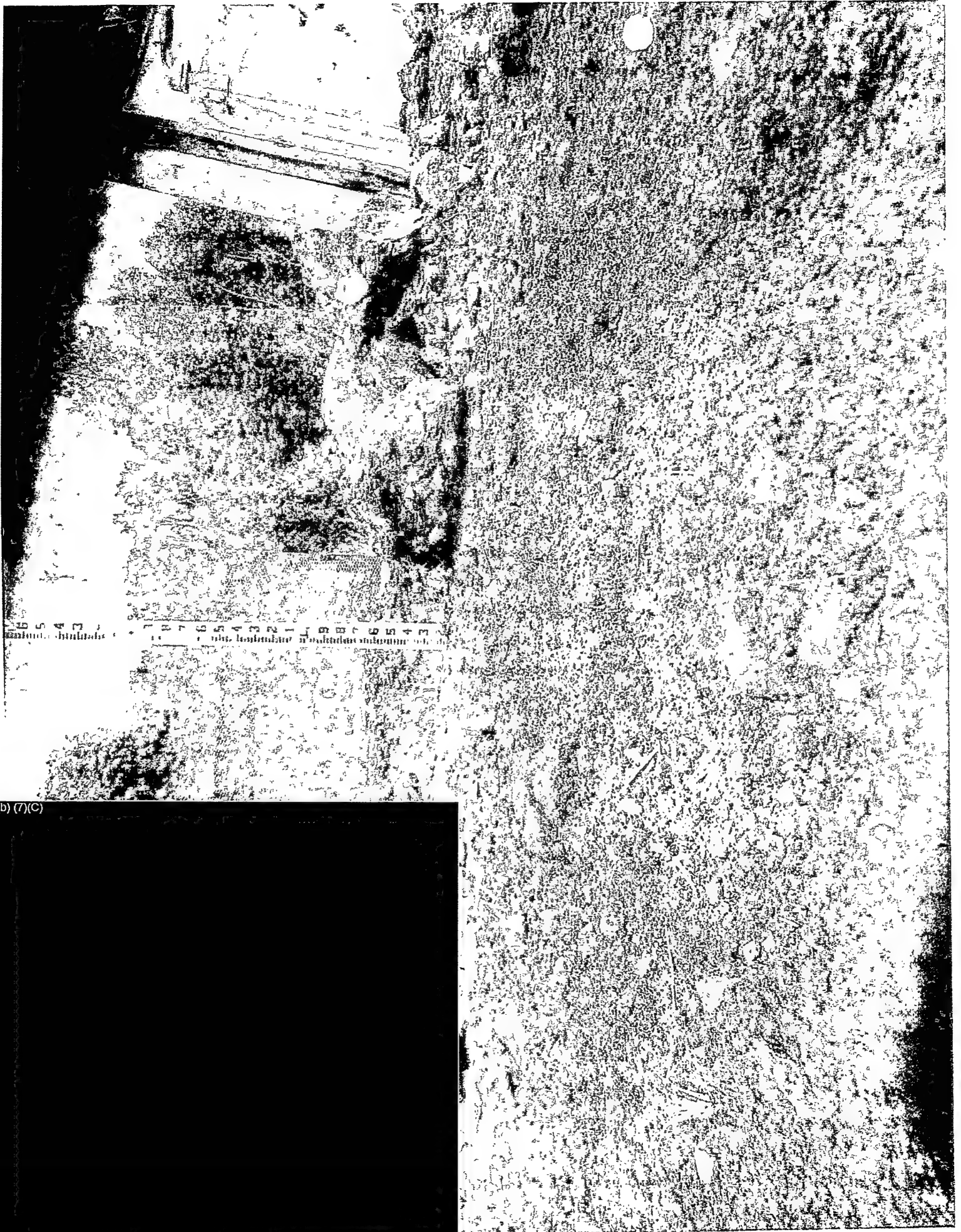
1900.

ALBANY: J. B. LIPPINCOTT & COMPANY, PRINTERS.

1900.

ALBANY: J. B. LIPPINCOTT & COMPANY, PRINTERS.





(b) (7)(C)



Office of the General Counsel
Osborne Administration Building, Suite 109
915 Bull Street
Columbia, SC 29208

August 17, 2020

Mr. Russ Kick
Open Records Specialist
New England Anti-Vivisection Society (NEAVS)
333 Washington Street, Suite 850
Boston, MA 02108

Dear Mr. Kick,

In response to your Freedom of Information Act request, enclosed please find the most recent AAALAC International Program Description created by the University of South Carolina. This includes all appendices and attachments.

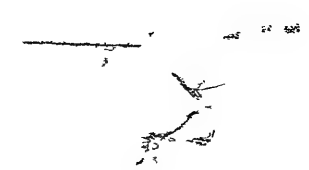
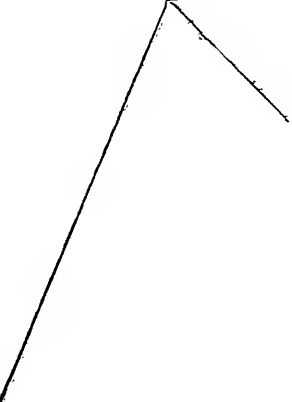
The search, retrieval and redaction of this document took 5 hours at \$15.00 per hour. Therefore, no additional payment is required as your \$75.00 deposit will cover the cost of production.

Please feel free to contact me with any questions or concerns.

Sincerely,

Susan H. Nelson

Enclosure





UNIVERSITY OF
SOUTH CAROLINA

Office of Research

Institutional Animal Care
and Use Committee

MEMORANDUM

TO: Dr. Prakash Nagarkatti
Vice President for Research

Mr. Thomas Coggins
Institutional Official and Director, Office of Research Compliance

FROM: Institutional Animal Care and Use Committee

DATE: March 7, 2019

SUBJECT: Semiannual Evaluation of Animal Care and Use Program and
Inspection of Facilities

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the *Guide for the Care and Use of Laboratory Animals* (Guide), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA

Departures from the PHS Policy, the *Guide*, and the AWA.

Select A or B:

- ☒ A. There were no departures during this reporting period.
☐ B. The following departures have been reviewed and approved by the IACUC:

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s): March 7, 2019

Select A or B:

- ☒ A. There were no deficiencies in the program during this reporting period.
☐ B. The following deficiencies have been identified:

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s): February 15-26, 2019

Select A or B:

- ☐ A. There were no deficiencies in the animal facility during this reporting period.
☒ B. The following deficiencies have been identified: *See attached table.*

IV. Minority Views

Select A or B:

- ☒ A. No minority views were submitted or expressed.
☐ B. The following minority views were expressed:

V. Status of AAALAC Accreditation [*identify accredited facilities, if applicable*]

Accredited facilities include:

USC main campus and the School of Medicine (SOM).

Handwritten scribbles and marks at the top of the page, possibly representing a signature or initials.

Year	Spr/Fall	Bldg	Room	A/M/S	Problem	Correction	Date	Responsible	Date for correction
2019	Spr	DSC	112	m	sharp box full	replace sharps container	2/26/2019	PI	3/8/2019
2019	Spr	DSC	120	m	full sharps container; large syringe with open needle on shelf; uncovered clean cages outside room	change sharps container; dispose of properly in sharps container; cover clean cages	2/26/2019	PI	3/8/2019
2019	Spr	DSC	123	m	cover next to the light switch needs to be sealed	replace electrical covers	2/26/2019	DLAR	8/1/2019
2019	Spr	DSC	124	m	missing electrical covers	replace electrical covers	2/26/2019	DLAR	8/1/2019
2019	Spr	DSC	124	m	Rack 2 date missing	clean/sanitize cage racks	2/26/2019	DLAR	3/8/2019
2019	Spr	DSC	125	m	Cage cards	Complete cage cards with necessary information	2/26/2019	DLAR	3/8/2019
2019	Spr	DSC	128	m	food bin label- incomplete dates	properly label food bins with mill date and open date	2/26/2019	DLAR	3/8/2019
2019	Spr	DSC	130	m	wadded up dirty lab coat in vestibule	clean and store lab coats properly	2/26/2019	PI	3/8/2019
2019	Spr	DSC	132	m	missing electrical covers	replace electrical covers	2/26/2019	DLAR	3/8/2019
2019	Spr	DSC	309	m	eyewash out of date 5/17	Inspect eyewash	2/26/2019	Facilities	inspect monthly
2019	Spr	DSC	311	m	cabinets dirty outside	clean cabinets	2/26/2019	PI	
2019	Spr	DSC	312	m	eyewash out of date 12/18	Inspect eyewash	2/26/2019	Facilities	Inspect monthly
2019	Spr	DSC	326	m	eyewash out of date	Inspect eyewash	2/26/2019	PI	Inspect monthly
2019	Spr	DSC	119E	m	cage cards	Complete cage cards with necessary information	2/26/2019	PI	3/8/2019
2019	Spr	DSC	130B	m	unlabeled food bin in cart	properly label food bins with mill date and open date	2/26/2019	PI	3/8/2019
2019	Spr	DSC	337A	m	unlabeled ziploc bag of food; dirty chairs; dirty cart	properly label food with mill date and open date; remove chairs, clean/sanitize cart	2/26/2019	PI	3/8/2019
2019	Spr	DSC	337C	m	food pellets on cart (attracts vermin)	clean/sanitize cart	2/26/2019	PI	3/8/2019
2019	Spr	DSC	DLAR	m	dirty laundry room	clean room	2/26/2019	DLAR	3/8/2019
2019	Spr	DSC	DLAR	m	uncovered rat cage supplies in the hallway	cover supplies	2/26/2019	DLAR	3/8/2019
2019	Spr	DSC	DLAR	m	hallways and cagewash are dirty	clean	2/26/2019	DLAR	3/8/2019
2019	Spr	DSC	DLAR hallway	m	using dirty rat cages to store equipment in the hallway; feces and dirty bedding were present	clean/sanitize cages; store equipment properly	2/26/2019	PI	3/8/2019

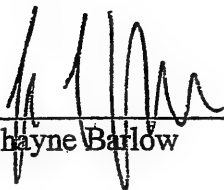
Year	Spr/Fall	Bldg	Room	A/M/S	Problem	Correction	Date	Responsible	Date for correction
2019	Spr	GSRC	28	m	cardboard in fridge	remove cardboard	2/15/2019	PI	3/8/2019
2019	Spr	GSRC	cagewash	m	uncovered clean cages	cover clean cages	2/15/2019	DLAR	2/22/2019
2019	Spr	SOM01	C05	m	vaporizer service overdue	get vaporizer recertified	2/25/2019	PI	1-Aug-19
2019	Spr	SOM01	C05	m	unsecured O2 tanks	O2 tanks must be secured at all times	2/25/2019	PI	2/27/2019
2019	Spr	SOM01	C15	m	hood used for animal work is extremely dirty	clean animal use area in hood	2/25/2019	PI	3/10/2019
2019	Spr	SOM01	C46	m	Unattended animals in unsecured lab: 2 cages of animals without food or water, plus one animal under anesthesia in surgical area; Controlled drug (ketamine/xylozine) mixed 1/11/19 and unsecured; vaporizer service overdue; controlled drugs (Fatal-Plus) with expiration date missing and unsecured on countertop	Do not leave any animals unattended in unsecured areas; do not leave anesthetized mice unattended; mix fresh batch for each surgical date; get vaporizer recertified; no food/drink allowed in animal work areas; compounds must be date labelled	2/25/2019	PI	2/25/2019
2019	Spr	SOM01	D7	m	liquid in container not marked properly	liquids must be labelled and dated	2/25/2019	PI	3/1/2019
2019	Spr	SOM01	D7a	m	vaporizer out of date	get vaporizer recertified	2/25/2019	PI	
2019	Spr	SOM04	A21	m	food bin expired	provide in-date food	2/25/2019	DLAR	3/1/2019
2019	Spr	SOM04	A25	m	power strip in sink, plugged in	disconnect power strip and do not place in sink	2/25/2019	PI	2/25/2019
2019	Spr	SOM04	A31	m	Racks out of date	clean/sanitize cage racks	2/25/2019	DLAR	3/1/2019

Year	Spr/Fall	Bldg	Room	A/M/S	Problem	Correction	Date	Responsible	Date for correction
2019	Spr	SOM04	A37	m	wet bedding in cages	supply dry bedding cage	2/25/2019	PI	2/25/2019
2019	Spr	SOM04	A39	m	food bin has no mill or open date	properly label food bins with mill date and open date	2/25/2019	PI	3/1/2019
2019	Spr	SOM04	C16	m	rack out of date	clean/sanitize cage racks	2/25/2019	DLAR	3/4/2019
2019	Spr	SOM04	C20	m	bottle on equipment near outlet/ surge protector	bottles must be labelled and dated	2/25/2019	PI	3/10/2019
2019	Spr	SOM04	C21	m	eyewash out of date 1/17/19	inspect eyewash	2/25/2019	Facilities	8/30/2019
2019	Spr	SOM04	cagewash	m	water on floor in clean side- maybe from autoclave	repair/ keep floor dry	2/25/2019	DLAR	4/27/2019
2019	Spr	SOM04	cold food storage	m	food stored in cardboard, in plastic tub	remove cardboard	2/25/2019	PI	2/27/2019
2019	Spr	SOM04	food room	m	no certification date on biosafety hood	certify or remove from service	2/25/2019	DLAR	3/1/2019
2019	Spr	SOM04	Rack wash	m	Interior Emergency Exit sign is peeling off	Replace Emergency Exit sticker	2/25/2019	DLAR	3/1/2019
2019	Spr	SOM04	throughout	m	Racks out of date	clean/sanitize cage racks	2/25/2019	DLAR	3/1/2019

VI. Signatures



Dr. Shannon Davis



Dr. Shayne Barlow

REDACTED

By signing the above, I hereby declare the Semiannual Program Review and Facilities Inspection Summary for Fall 2019 to be accurate to the best of my knowledge.



UNIVERSITY OF
SOUTH CAROLINA

Office of Research

Institutional Animal Care
and Use Committee

MEMORANDUM

TO: Dr. Prakash Nagarkatti
Vice President for Research

Mr. Thomas Coggins
Institutional Official and Director, Office of Research Compliance

FROM: Institutional Animal Care and Use Committee

DATE: September 18, 2019

SUBJECT: Semiannual Evaluation of Animal Care and Use Program and
Inspection of Facilities

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the *Guide for the Care and Use of Laboratory Animals* (Guide), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA

Departures from the PHS Policy, the *Guide*, and the AWA.
Select A or B:

- ☒ A. There were no departures during this reporting period.
☐ B. The following departures have been reviewed and approved by the IACUC:

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s): September 5, 2019

Select A or B:

- ☒ A. There were no deficiencies in the program during this reporting period.
☐ B. The following deficiencies have been identified:

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s): August 26-28, 2019

Select A or B:

- ☐ A. There were no deficiencies in the animal facility during this reporting period.
☒ B. The following deficiencies have been identified: *See attached table.*

IV. Minority Views

Select A or B:


- ☒ A. No minority views were submitted or expressed.
☐ B. The following minority views were expressed:

V. Status of AAALAC Accreditation [*identify accredited facilities, if applicable*]

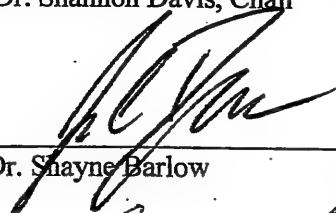
Accredited facilities include:

USC main campus and the School of Medicine (SOM).

VI. Signatures



Dr. Shannon Davis, Chair



Dr. Shayne Barlow

REDACTED

By signing the above, I hereby declare the Semiannual Program Review and Facilities Inspection Summary for Fall 2019 to be accurate to the best of my knowledge.

Fall 2019 Semi-annual Inspection Results

1/4

10/2/2019 11:42 AM

Year	Spr/Fall	Bldg	Room	A/M/S	Problem	Correction	Date	Responsible	Date for correction
2019	Fall	CLS	006B	m	AUP number not found	Label housing or room with AUP number	8/26/2019	PI	immediately
2019	Fall	DSC	120	m	Sharps container full	Replace sharps container	8/28/2019	DLAR	9/30/2019
2019	Fall	DSC	125	m	Dirty hood	Clean animal use area	8/28/2019	PI	9/30/2019
2019	Fall	DSC	129	m	Full sharps container	Replace sharps container	8/28/2019	DLAR	9/30/2019
2019	Fall	DSC	131	m	Sharps container full	Replace sharps container	8/28/2019	DLAR	9/30/2019
2019	Fall	DSC	132	m	Outlet covers missing	Replace outlet covers	8/28/2019	Dept (EXSCI)	9/30/2019
2019	Fall	DSC	132	m	Door signage assigns room to PI not at USC	Update contact information	8/28/2019	DLAR	9/30/2019
2019	Fall	DSC	308	m	Signage - contact information out of date	Update contact information for dexa	8/28/2019	Dept (EXSCI)	9/30/2019
2019	Fall	DSC	308	m	Eyewash out of date 3/17	Inspect eyewash	8/28/2019	Facilities	9/30/2019
2019	Fall	DSC	308	m	Overflowing trash onto floor	Empty trash according to biohazard protocols	8/28/2019	PI	9/30/2019
2019	Fall	DSC	308	m	Vaporizer on surgivet out of date 2003	Get vaporizer recertified	8/28/2019	PI	9/30/2019
2019	Fall	DSC	309	m	Bell jar extremely dirty, is in use per students in room	Clean animal use areas and bell jar in fume hood	8/28/2019	PI	9/30/2019
2019	Fall	DSC	313	m	Eyewash out of date	Inspect eyewash	8/28/2019	Facilities	9/30/2019
2019	Fall	DSC	313	m	Open drinking water container on bench	No food/drink in lab areas	8/28/2019	PI	9/30/2019
2019	Fall	DSC	313	m	Exposed sharps on bench	Dispose of in sharps container	8/28/2019	PI	9/30/2019
2019	Fall	DSC	313	m	Cardboard in room	Remove cardboard	8/28/2019	PI	9/30/2019
2019	Fall	DSC	112 Procedure Room	m	Unsecure oxygen tanks	Oxygen tanks must be secure at all times	8/28/2019	DLAR	9/30/2019
2019	Fall	DSC	120 Procedure Room	m	Sharps container full	Replace sharps container	8/28/2019	DLAR	9/30/2019
2019	Fall	DSC	129C	m	Racks overdue for cleaning	Clean/sanitize cage racks	8/28/2019	DLAR	immediately
2019	Fall	DSC	131 Procedure Room	m	Full sharps container,	Replace sharps container	8/28/2019	PI	9/30/2019
2019	Fall	DSC	Food Storage	m	Mill dates on food obstructed	Arrange food so mill date can be read	8/28/2019	DLAR	9/30/2019
2019	Fall	DSC	Food Storage	m	Dates on PI diet in cooler illegible	Arrange food so mill date can be read, ensure labels are easily read	8/28/2019	PI	9/30/2019
2019	Fall	GSRC	2	m	Sharps container full	Replace sharps container	8/26/2019	DLAR	9/30/2019
2019	Fall	GSRC	6	m	Fire extinguisher out of date 4/19	Inspect fire extinguisher	8/26/2019	Facilities	9/30/2019
2019	Fall	GSRC	9	m	Non-operable vaporizer is not labelled	Label vaporizer as non-operable	8/26/2019	DLAR	9/30/2019

Fall 2019 Semi-annual Inspection Results

2/4

10/2/2019 11:42 AM

Year	Spr/Fall	Bldg	Room	A/M/S	Problem	Correction	Date	Responsible	Date for correction
2019	Fall	GSRC	9	m	Cardboard boxes in storage closet	Dispose of cardboard (attracts vermin)	8/26/2019	DLAR	9/30/2019
2019	Fall	GSRC	11	m	Uncovered waterbottles; food out of date - milled 1/22/19, opened 7/3/19; unlabeled food bin cart	Cover clean waterbottles, provide in-date food, properly label food bins with mill date and open date	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	11	m	Uncovered waterbottles, food out of date- 1/22 7/3, unlabeled food bin cart, cage cards lacking contact information (chen 2391)	Refill halo bottles, service faucet, cover clean waterbottles, provide in-date food, properly label food bins with mill date and open date, update contact information on cage cards	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	14	m	Cloth chair in room	Remove cloth chairs from room - cannot be sanitized	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	14	m	Room is dirty/cluttered	Clean up and organize	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	14	m	Cardboard boxes present	Remove and dispose of cardboard (attracts vermin)	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	33	m	Cage cards lack contact information (2332, 2425)	Update contact information on cage cards	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	34	m	Cage cards with incorrect AUP number	Update AUP information on cage cards	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	38	m	Unable to locate hood date	Certify hood or remove from service	8/26/2019	DLAR	Immediately
2019	Fall	GSRC	13, 30, 38	m	Unlabeled spray bottles	Label spray bottles with contents	8/26/2019	DLAR	9/30/2019
2019	Fall	GSRC	337 Behavior Lab	m	No sharps container in room	Provide sharps container	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	35A	m	Sharps container full in prep room	Replace sharps container	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	35A	m	Cage cards with incorrect AUP number	Update AUP information on cage cards	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	35A-C	m	Singly housed animal card incomplete	Completely fill out singly housed animal cards	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	35B	m	Clean caging in prep room should be covered	Use proper/clean covers over clean supplies	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	35B	m	Rack 63 - illegible cage cards	Replace cage cards with complete/current information	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	35C	m	Cage cards incomplete	Update cage cards with complete information	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	39A	m	Vaporizer out of date	Recertify vaporizer	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	39A	m	IVIS out of date 6/18	Inspect/recertify IVIS	8/26/2019	PI	9/30/2019

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Fall 2019 Semi-annual Inspection Results

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Year	Spr/Fall	Bldg	Room	A/M/s	Problem	Correction	Date	Responsible	Date for correction
2019	Fall	GSRC	39A	m	Unlabeled and expired agents present	Properly label and/or dispose of expired agents according to protocol	8/26/2019	PI	9/30/2019
2019	Fall	GSRC	39A	m	Sharps container full	Replace sharps container	8/26/2019	PI	immediately
2019	Fall	GSRC	Clean CW	m	Bedding stored against wall	Store bedding 6 inches away from wall	8/26/2019	DLAR	9/30/2019
2019	Fall	GSRC	Clean CW	m	Water bottles are uncovered	Cover clean supplies	8/26/2019	DLAR	9/30/2019
2019	Fall	GSRC	DLAR	m	IACUC Posters: chair contact out of date	Update IACUC chair contact information	8/26/2019	DLAR	9/30/2019
2019	Fall	GSRC	DLAR	m	hoods out of date	recertify hoods	8/26/2019	DLAR	9/30/2019
2019	Fall	GSRC	Food Storage	m	Cardboard	Remove cardboard	8/26/2019	PI	9/30/2019
2019	Fall	SOM	A25	m	Contact information out of date	Update contact information on cage cards	8/27/2019	PI	9/30/2019
2019	Fall	SOM	A26	m	Uncovered cages and water on cart	Cover clean supplies	8/27/2019	PI	9/30/2019
2019	Fall	SOM	A9	m	Trash overflowing (biohazard)	Trash must be emptied and removed according to biosafety protocol when full	8/27/2019	DLAR	immediately
2019	Fall	SOM	A31	m	Cage cards lacking information (2343, 2428)	Update information on cage cards	8/27/2019	PI	9/30/2019
2019	Fall	SOM01	B48	m	Eyewash out of date	Inspect eyewash monthly	8/27/2019	Facilities	9/30/2019
2019	Fall	SOM01	B48A Surgery Suite	m	Fire extinguisher last inspected 5/2019	Inspect extinguisher monthly	8/27/2019	Facilities	9/30/2019
2019	Fall	SOM01	C14	m	Feces, bedding, etc. in working area of fume hood	Clean animal use area	8/27/2019	PI	9/30/2019
2019	Fall	SOM01	C15	m	Cloth covered chairs in room	Remove cloth chairs from room (can't be sanitized)	8/27/2019	PI	9/30/2019
2019	Fall	SOM01	C15	m	Feces in fume hood	Clean animal use area	8/27/2019	PI	9/30/2019
2019	Fall	SOM01	C56	m	Mouse waste on counter	Clean animal use area	8/27/2019	PI	9/30/2019
2019	Fall	SOM01	D36	m	Eyewash out of date 11/2018	Inspect eyewash monthly	8/27/2019	Facilities	9/30/2019
2019	Fall	SOM01	D45	m	Eyewash out of date 11/2018	Inspect eyewash monthly	8/27/2019	Facilities	9/30/2019
2019	Fall	SOM01	D45	m	Sharps container full	Replace sharps container immediately	8/27/2019	PI	9/30/2019
2019	Fall	SOM01	D46	m	Eyewash out of date 11/2018	Inspect eyewash monthly	8/27/2019	Facilities	9/30/2019
2019	Fall	SOM01	D48	m	Eyewash out of date 10/18	Inspect eyewash monthly	8/27/2019	Facilities	9/30/2019
2019	Fall	SOM01	D52	m	Dirty work area under hood	Clean animal use area	8/27/2019	PI	9/30/2019
2019	Fall	SOM01	D52	m	Dirty cage in room	Take dirty caging to cagewash	8/27/2019	PI	9/30/2019
2019	Fall	SOM02	C4	m	Sharps container full	Replace sharps container immediately	8/27/2019	PI	9/30/2019
2019	Fall	SOM04	C16	m	Trash overflowing (biohazard)	Empty trash according to biohazard protocols	8/27/2019	PI	9/30/2019

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Fall 2019 Semi-annual Inspection Results

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Year	Spr/Fall	Bldg	Room	A/M/S	Problem	Correction	Date	Responsible	Date for correction
2019	Fall	SOM04	C16	m	Eye lube expired: 11/18 (x1), 9/18 (x2)	Dispose of expired materials	8/27/2019	PI	9/30/2019
2019	Fall	SOM04	C20	m	Bedding container is open	Keep bedding container sealed	8/27/2019	PI	9/30/2019
2019	Fall	n/a	n/a	m	2 Renewal approved after anniversary date				

22